

11-07-91  
Vol. 56 No. 216  
ges 56919-57230

Thursday  
November 7, 1991

# Federal Register

Briefing on How To Use the Federal Register  
For information on a briefing in Washington, DC, see  
announcement on the inside cover of this issue.





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## THE FEDERAL REGISTER

### WHAT IT IS AND HOW TO USE IT

- FOR:** Any person who uses the Federal Register and Code of Federal Regulations.
- WHO:** The Office of the Federal Register.
- WHAT:** Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
  2. The relationship between the Federal Register and Code of Federal Regulations.
  3. The important elements of typical Federal Register documents.
  4. An introduction to the finding aids of the FR/CFR system.
- WHY:** To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

### WASHINGTON, DC

- WHEN:** November 25, at 9:00 a.m.
- WHERE:** Office of the Federal Register,  
First Floor Conference Room,  
1100 L Street NW., Washington, DC.
- RESERVATIONS:** 202-523-5240.
- DIRECTIONS:** North on 11th Street from Metro Center to southwest corner of 11th and L Streets



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# Presidential Documents

Title 3—

The President

Proclamation 6369 of November 5, 1991

National Hospice Month, 1991 and 1992

By the President of the United States of America

## A Proclamation

Dedicated to serving terminally ill persons and their families, hospice programs have become an important part of our Nation's health care system. This month, we gratefully salute the many outstanding professionals and volunteers who provide hospice care.

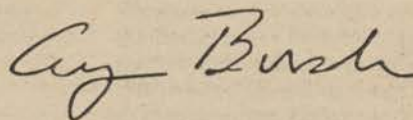
By offering a positive and supportive environment, as well as high quality medical care, hospice programs enable terminally ill persons to live peacefully and comfortably in their final days. In so doing, these facilities and services not only reaffirm the inherent dignity and worth of every individual but also demonstrate reverence for human life in all its stages. Relying on the combined knowledge, skills, and compassion of a full team of professionals and volunteers—including physicians, nurses, counselors, therapists, and members of the clergy—hospice programs also help patients' families to cope with their bereavement.

As hospice personnel well know, caring for terminally ill persons can be physically and emotionally exhausting. Fortunately, the establishment of a permanent Medicare hospice benefit and an optional Medicaid hospice benefit has made it possible for more Americans to obtain needed medical and support services. In addition, concerned individuals and agencies in both the public and private sectors have maintained strong working relationships in the interest of hospice care benefits.

In recognition of the importance of hospice programs and in honor of the many dedicated professionals and volunteers who care for terminally ill persons, the Congress, by Public Law 102-121, has designated November 1991 and November 1992 as "National Hospice Month" and has authorized and requested the President to issue a proclamation in observance of these months.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim November 1991 and November 1992 as National Hospice Month. I encourage all Americans, as well as government officials and health care providers, to observe these months with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of November, in the year of our Lord nineteen hundred and ninety-one, and of the Independence of the United States of America the two hundred and sixteenth.





# Presidential Documents

Executive Order 11629  
National Hispanic Month, 1961 and 1962

By the President of the United States of America

A Proclamation

It is the policy of the United States to encourage the participation of all Americans in the national life, and to recognize the contributions of all Americans to the Nation's progress and well-being.

Hispanic Americans, who constitute a significant and growing portion of the Nation's population, have made outstanding contributions to the Nation's culture, science, industry, and commerce. Their achievements are a source of pride and inspiration to all Americans.

It is the policy of the United States to encourage the participation of all Americans in the national life, and to recognize the contributions of all Americans to the Nation's progress and well-being.

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Hispanic Americans, who constitute a significant and growing portion of the Nation's population, have made outstanding contributions to the Nation's culture, science, industry, and commerce.

*Lyndon B. Johnson*



# Rules and Regulations

Federal Register

Vol. 56, No. 216

Thursday, November 7, 1991

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## NATIONAL CREDIT UNION ADMINISTRATION

### 12 CFR Part 709

#### Involuntary Liquidation of Federal Credit Unions and Adjudication of Creditor Claims Involving Federally Insured Credit Unions in Liquidation

**AGENCY:** National Credit Union Administration (NCUA).

**ACTION:** Final rule.

**SUMMARY:** The NCUA is issuing a new part 709 to its Rules and Regulations. This rule sets forth procedures applicable to revocations of charter and involuntary liquidations of Federal credit unions pursuant to 12 U.S.C. 1787(A)(1)(A), (B). It also sets forth procedures applicable to involuntary liquidations and adjudication of creditor claims against all federally insured credit unions. The Board believes this regulation will provide guidance to its employees conducting liquidations and to claimants seeking to assert a claim against a credit union in liquidation.

**EFFECTIVE DATE:** November 7, 1991.

**ADDRESSES:** National Credit Union Administration, 1776 G Street, NW., Washington, DC 20456.

**FOR FURTHER INFORMATION CONTACT:** John K. Ianno, Trial Attorney, Office of General Counsel, NCUA, at the above address, or telephone: (202) 682-9630.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

The NCUA has statutory authority to liquidate insolvent Federal credit unions pursuant to 12 U.S.C. 1787(a)(1)(A). Upon appointment by the appropriate state authorities, NCUA also acts as liquidating agent for insolvent, state-chartered federally insured credit unions. 12 U.S.C. 1787(j). As liquidating agent of federally insured credit unions, the NCUA has broad powers to act in

place of former officials of the institution and do all things necessary to wind up the affairs of the institution. These powers help assure that credit union members receive prompt access to their funds and also assure that NCUA is able to fulfill its obligation to minimize the cost of a liquidation to the National Credit Union Share Insurance Fund, thereby protecting the Fund's assets.

Both the Financial Institutions Reform, Recovery and Enforcement Act (FIRREA) (1989) and the Crime Control Act (1990) provide explicit language concerning NCUA's duties and responsibilities as liquidating agent. FIRREA also provides a framework for adjudication of creditor claims and requires NCUA to provide for alternative dispute resolution of claims.

Congress recognized that this detailed statutory scheme would likely require implementing regulations and specifically authorized the Board to regulate in this area. See 12 U.S.C. 1787(b)(1), (4).

This regulation addresses the powers and duties of NCUA as liquidating agent and establishes creditor claims adjudication and alternative dispute resolution procedures. It does not apply to insurance claims arising out of the liquidation of a federally insured credit union. Insurance claims are decided pursuant to part 745 of NCUA's Rules and Regulations. (See 12 CFR part 745, subpart B.) The Board believes this regulation will provide guidance to its employees conducting liquidations and to claimants seeking to assert a claim against a credit union in liquidation.

##### B. Comments

The NCUA Board issued a proposed rule on May 29, 1991, with a 60-day comment period (56 FR 24147, 5/29/91). Eight public comment letters were received. Three were from state credit union leagues, two were from national credit union trade associations, two were from law firms which represent credit unions and one was from a federal credit union. All of the commenters, except one state credit union league, agreed in general with the proposed rule.

##### C. Discussion

Section 709.0 sets forth the scope of part 709, and § 709.1 contains definitions used in this Part. This regulation

addresses the powers, duties and responsibilities of the NCUA Board and follows the authority granted to the Board as liquidating agent pursuant to Federal law. See 12 U.S.C. 1787.

Two commenters noted that the regulation does not indicate how NCUA may become liquidating agent for a state-chartered federally insured credit union. The NCUA Board does not have the authority to appoint itself liquidating agent for a state-chartered federally insured credit union. The Board must be appointed by the appropriate state regulatory authority. See 12 U.S.C. 1787(a)(1)(B), (j). Once appointed, the Board then possesses all the rights, powers, and privileges granted by state law to a liquidating agent of a state-chartered credit union. One commenter noted that the regulation establishes a payout priority in an attempt to preempt state law when the Board acts as liquidating agent for state-chartered credit unions. State law will be followed to the extent that it does not conflict or interfere with the Board's statutory authority. Whether a particular state's statute providing for a payout priority different from that established in this regulation is preempted will depend upon the substantive effect of that statute. Generally, the Board believes this is a non-issue because the major claimant against a credit union's assets is the NCUSIF based on its insurance payout and, in reality, it will receive its funds after all other claimants.

Section 709.2 provides that the Board, by operation of law, becomes successor in interest to all rights, powers, and privileges of the credit union and its members, officials and shareholders. Once the Board is appointed liquidating agent, members, officials and shareholders no longer have any right to act on behalf of the credit union. The Board, as liquidating agent, has the right to possession of all assets and property of every description of the credit union.

One commenter objected to the use of the term shareholder stating that members are the owners of the credit union. While it is correct that only members are owners of a credit union, the Board notes that the language in this section tracks the language of 12 U.S.C. 1787(b)(2)(B)(i) which specifically refers to shareholders. However, 12 U.S.C. 1787(b)(2)(A)(i) refers to "accountholders" and 12 U.S.C. 1787(b)(2)(C) refers to "stockholder".



Therefore, the Board has added a new definition "shareholder" as an all inclusive term meaning any party that is the owner of a share, share certificate, or share draft account, or their equivalent under state law, including members and nonmembers. See § 709.1 of this part. Accordingly, depending upon the context of the provision, the Board has either deleted the term "members" or replaced it with the term "shareholders".

Section 709.3 sets forth the manner in which officials of a Federal credit union placed into liquidation by the NCUA Board may challenge that action. The board of directors of the credit union in liquidation may meet for the sole purpose of considering and authorizing an action in the name of the credit union to challenge the liquidation. Such an action must be brought in the United States District Court for the district where the credit union is located or the United States District Court for the District of Columbia. The action must be commenced not later than 10 days after the date on which the NCUA Board closes the credit union for liquidation. One commenter noted that the right to challenge an involuntary liquidation by the NCUA should be vested in the shareholders. The board of a credit union is elected by the membership. The NCUA Board considers it appropriate to provide that the credit union's board, as elected representatives of the membership, should vote to authorize a challenge of NCUA's action by the credit union.

Section 709.3 also provides that "No credit union funds are available to pay the legal expenses of a challenge." Seven letters objected to this language. Each commenter argued that this prohibition effectively deprives the credit union's shareholders of due process.

The Board, when acting as liquidating agent, has a fiduciary obligation to conserve the assets of the credit union to assure that creditors and shareholders receive as much money as possible upon completion of the liquidation. This obligation is at odds with advancement of funds to challenge the very action the Board has undertaken. Advancement of funds encourages frivolous challenges that only further dissipate credit union assets. Moreover, there is no statutory requirement in the Federal Credit Union Act requiring that legal fees be made available to challenge an involuntary liquidation. Congress chose to address legal fees only in connection with actions pursuant to section 206 of the Federal Credit Union Act. See 12 U.S.C.

1786(p). The language in that section provides a court, upon application, with discretion to award fees. Significantly, 12 U.S.C. 1787 of the Federal Credit Union Act is silent on the question of legal fees for a challenge. Given this silence, the Board believes it would be inappropriate, as liquidating agent, to advance funds of the credit union to challenge its action.

The right to access the courts to challenge an action and the right to have the challenge paid for are distinguishable. This regulation does not establish an absolute bar to payment of legal fees or eliminate a credit union's access to the courts. A credit union may still challenge NCUA's action by retaining counsel on a contingent fee basis. This was recently recognized in *Federal Sav. & Loan Ins. v. Angell, Holmes & Lea & Van Voorhis & Skaggs*, 838 F.2d 395 (9th Cir. 1988) modified 842 F.2d 239 (9th Cir. 1988) cert. denied 488 U.S. 848 (1988). In that case, the court concluded that a savings association seeking to challenge an involuntary receivership was not without a remedy, absent advancement of legal fees, in that it could challenge by hiring counsel on a contingent basis. Obviously, if the NCUA's action is enjoined by the district court and the credit union is returned to the membership, fees would be available from the assets of the credit union.

Also in connection with § 709.3, two commenters urged the NCUA Board to provide for a pre-seizure hearing or conservatorship prior to placing a Federal credit union into involuntary liquidation. It is well established that pre-hearing seizures are constitutionally permissible provided post-seizure review is granted. See *Fahey v. Mallonee*, 332 U.S. 245 (1947). In addition, the legislative history and statutory scheme contemplate quick action to minimize loss to the Insurance Fund and avoid any loss of confidence in the Nation's financial system. Accordingly, the NCUA Board does not believe a pre-seizure hearing or conservatorship is warranted. It should be noted that in cases where insolvency is not a basis for involuntary liquidation and, thus, expeditious action may not be necessary, administrative action is pursued under part 747, subpart E.

Section 709.4 sets forth the powers and duties of the liquidating agent. Subsection (a) requires the liquidating agent to promptly inventory the credit union's assets. Subsection (b) requires the liquidating agent to promptly publish a notice to creditors to present their claims by a specified date, not less than 90 days after initial publication. A

similar notice must be mailed to all creditors listed on the credit union's books. The liquidating agent is required to republish the notice one and two months after the initial publication. These subsequent publications do not extend the date by which creditors must file their claims with the liquidating agent.

Subsection 709.4(c) states the liquidating agent's broad discretionary authority to collect all obligations due the credit union and do all other things, consistent with Federal law, desirable or expedient to wind up the affairs of the credit union. This includes *inter alia* the liquidating agent's authority to dispose of assets of the credit union and repudiate contracts. In this regard, § 709.4(c) has been clarified by adding "disaffirmance or repudiation" to the clause in paragraph (6). The statutory basis for this broad authority is 12 U.S.C. 1787(b)(2). Although subsection (c) sets forth many of those things a liquidating agent will be required to do in connection with winding up the affairs of a credit union, it is not intended to be all-inclusive. When liquidating state-chartered federally insured credit unions, in addition to the powers provided under Federal law, the liquidating agent has all the powers and privileges granted a liquidating agent pursuant to state law. See 12 U.S.C. 1787(j).

Two commenters suggested that the regulation expressly require that the liquidating agent file documents or record liens as necessary to perfect any interest acquired in property. The NCUA Board believes that the liquidating agent has this responsibility pursuant to § 709.4(c)(5).

Subsection 709.4(d) sets forth the liquidating agent's authority to expend funds from the liquidated estate for liquidation expenses. This authority is consistent with statutory authority contained in 12 U.S.C. 1787(b)(2). An illustrative list of the types of assets commonly present in a liquidation is included in this section.

Section 709.5 sets forth the provisions relating to priority of payouts from the liquidation estate. Under subsection (a), secured creditors will receive their security to the extent of their claim. The value of any security will be established to the satisfaction of the liquidating agent.

One commenter requested clarification regarding who has the burden of demonstrating the value of any security. The burden is on the creditor. Although it is impossible to identify how that value would be established in every case, the



expectation is that it would be done in a commercially reasonable manner. This will be determined by the type of security that is involved.

The second sentence of § 709.5(a) has been clarified. To the extent a claim of a secured creditor exceeds the value of the security, it is treated as an unsecured claim of a general creditor under subsection (b), the schedule of payout priorities. In this regard, the parenthetical phrase in § 709.5(b)(5) has also been clarified. This priority schedule is the same as that currently used in liquidations. Subsection (c) provides that the determination of priorities shall be based on the circumstances that exist on the date of the liquidation and subsection (d) provides that claims arising from repudiation or disaffirmance of any contract, including a lease, shall be considered claims by a general creditor for purposes of payout priority. The general policy that all claims in each category of payout priority should be paid in full before claims from a lower priority are paid is set out in subsection (e). The liquidating agent can, however, pay claims of a lower priority when he determines that adequate funds exist or will be recovered to pay all claims of a higher category in full and such action is reasonably necessary to conduct the liquidation.

One commenter noted that the language of the proposed regulation appears to give uninsured shareholders and the National Credit Union Administration Share Insurance Fund priority in receiving any surplus after all creditors, claimants and administrative expenses are paid. This was not the Board's intent. The National Credit Union Share Insurance Fund, or any other insurer of shares, are entitled to priority under paragraph (b)(6) of this Section only to the extent of their payment of share insurance. Language has been added indicating that if a surplus remains after making distribution in full on all allowed claims in every category, class or priority described in paragraphs (b)(1) through (b)(7) of this section, the surplus is to be distributed to the credit union's shareholders on a pro rata basis. This is consistent with 12 U.S.C. 1787(b)(11)(B). It should be noted, however, that such a surplus would be extremely rare.

Clarification has also been made to § 709.5(b)(6). It now reads as follows: "(6) shareholders to the extent of their respective uninsured shares and the National Credit Union Share Insurance Fund to the extent of its payment of share insurance."

Section 709.6 covers initial determinations of creditor claims.

Subsection (a) requires anyone who asserts a claim to do so in writing and to comply with the requirements specified in the notice to creditors. The claim must be submitted within the time provided for in the notice to creditors. Failure to file a timely claim shall be considered a waiver of the claim and shall constitute a bar to any rights or remedies with respect to the claim. All claimants, including those involved in litigation against the credit union at the time of liquidation, must file a claim within the period provided for in the notice. The filing of a claim and the exhaustion of administrative remedies is a prerequisite necessary to establish subject matter jurisdiction in the District Court over any action brought or continued against a credit union in liquidation. *Circle Industries, v. City Federal Sav. Bank*, 749 F.Supp. 447 (E.D.N.Y. 1990), *aff'd*, 931 F.2d 7 (2nd Cir. 1991).

One commenter points out that 12 U.S.C. 1787(b)(5)(c)(ii) provides a limited exception to the bar against filing a late claim. That Section provides that the liquidating agent has the discretion to consider an untimely claim provided the following two criteria are present: (1) The claimant did not receive notice of the appointment of the liquidating agent in time to file a claim before the date provided for in the Notice; and (2) the claim is filed in time to permit payment of the claim. This exception has been incorporated into the final regulation.

Under subsection 709.6(b), the liquidating agent has the discretion to request supplemental evidence in connection with a claim and may set reasonable limitations on the size and scope of supplemental evidence. The liquidating agent is required to compile a written record of a claim which he determines to be sufficient to provide a reasonable basis for a decision on the claim. Subsection (c) requires the liquidating agent to render a determination on a claim and notify the claimant within 180 days from the date the claim is filed; failure to render a determination within that time may be treated as a denial of the claim. The liquidating agent and the claimant may extend this period by written agreement. The last sentence of Subsection (c) has been clarified to make it consistent with the first sentence of that Subsection and the statute by adding "and notify the claimant" after the word "claim".

Two commenters objected to treating failure to respond as a denial noting that silence from the liquidating agent should not be considered adequate notice of a denial. It is the expectation of the NCUA Board that, when acting as liquidating agent, it will render a determination on

a claim within the prescribed or agreed time period. This language is provided to protect the claimant from procrastination by the liquidating agent. Consistent with the statute, it provides that the claimant may treat a failure by the liquidating agent to respond within the required or agreed to period as a denial and pursue other available remedies to satisfy the claim. A clarification to the last sentence in this section has also been made. That sentence now states "Failure by the liquidating agent to determine a claim within the 180-day period or, if the period is extended, within the extended period, shall be deemed a denial of the claim."

Subsections (d) and (e) require the liquidating agent, whenever a claim is disallowed in whole or in part, to provide a written explanation of the reasons for the action to the claimant. The claimant must also be informed of his appeal rights. Notice of a determination regarding a claim is sufficient if mailed to the claimant's most recent address appearing on the credit union's books, in the claim, or in the documents filed with the claim. If the liquidating agent disallows all or part of a claim, subsection (f) requires him to file with the Board, or its designated agent, a report of his determination. This report must contain the notice to the claimant and the findings by the liquidating agent on all relevant issues.

Section 709.7 sets forth the procedures for appealing the liquidating agent's determination. The claimant must choose one of three options within 60 days of the date of mailing of the initial determination by the liquidating agent. The three options are: (1) File an administrative appeal (as discussed in subsequent sections); (2) file a lawsuit against the liquidated credit union in the United States District Court having jurisdiction over the place where the credit union's principal place of business is located or in the United States District Court for the District of Columbia; or (3) continue a lawsuit commenced before the appointment of the liquidating agent. If the claimant fails to exercise one of these options within the 60-day period, the liquidating agent's determination will be final and the claimant will have no further rights with respect to the claim.

Section 709.8 governs administrative appeals. Subsection (a) is a general section addressing administrative appeals of the initial determination by the liquidating agent. Any request for an administrative appeal must be in writing, addressed to the Board, and



specify the type of appeal claimant desires. At this time, there are five types of administrative appeal which may be requested. Discussed in subsequent sections, they are: (1) Hearing on the record; (2) appeal to the Board; (3) mediation; (4) nonbinding arbitration; and (5) neutral fact finding. The determination of whether to agree to a request for an administrative appeal rests solely with the Board. The 60-day period for filing or continuing a lawsuit provided for in § 709.7 is tolled from the date of a request for administrative appeal to the date of the Board's decision regarding the request.

Subsection (b) provides that a hearing on the record will be conducted in accordance with subpart A, part 747 of NCUA's Rules and Regulations. The burden of proof rests with the claimant. Judicial review of a final decision, following a hearing on the record, must be filed within 30 days. Subsection (c) addresses alternative dispute resolution. Paragraph (1) sets forth the procedures applicable to a claimant who requests and receives authorization to appeal the initial determination directly to the Board. This is a written appeal; there is no right of personal appearance before the Board in connection with such an appeal. The appeal must identify the facts on which the request for review is based and identify the portion of the initial determination to which the claimant objects and the reasons for the objection. Any alleged error in the initial determination should be identified. Any evidence relied upon by the claimant which was not provided to the liquidating agent must be made available to the Board.

The Board will issue a decision on the claimant's appeal within 180 days of its receipt of the appeal. Failure to do so may be treated as a denial of the appeal. The Board's decision will be in writing and will constitute final agency action on the claim. Any request for judicial review of the Board's decision must be filed within 60 days of the date of the Board's decision or be forever barred. Judicial review shall be in accordance with chapter 7, title 5 of the U.S. Code in the Court of Appeals for the District of Columbia or the court of appeals for the judicial circuit where the credit union's principal place of business is located.

Paragraph (2) of subsection 709.8(c) provides the Board with the discretion to authorize mediation, nonbinding arbitration or neutral fact finding as means of alternative dispute resolution.

Four commenters focused on language in the proposed regulation which provides that these procedures may be available only at the discretion of the Board as being inconsistent with the

statute. The NCUA Board wishes to emphasize that its intent is not to discourage the use of alternative dispute resolution procedures. Nevertheless, 12 U.S.C. 1787(b)(7)(A) provides that these procedures will be available only if the Board agrees to them. Thus, the Board has discretion in this area.

Two commenters noted the summary treatment given this area and a third complained of a lack of incentive for creditors to choose this alternative. As noted, the Board does not wish to discourage use of these procedures. If these procedures are frequently requested by claimants, the Board will consider expanding available options in this area.

Section 709.9 discusses procedures for requesting expedited determination of a creditor claim in lieu of seeking a determination pursuant to the normal procedure in § 709.6.

As provided in subsection (a), the claimant has the burden of demonstrating a need for expedited relief. Claimant must show: (1) Presence of a valid and enforceable or perfected security interest in the assets of the credit union; and (2) that irreparable injury will occur if the normal claims procedure is followed. Under subsection (b), any request for expedited relief, in order to be considered, must be in writing and must be received by the Secretary of the NCUA Board within 30 days of the date of the liquidating agent's mailing of the notice to the creditor. A copy of the request must be simultaneously served on the liquidating agent for the credit union. There is no right of personal appearance before the Board in connection with such a request.

Subsection 709.9(c) provides that a request for expedited relief must include the following: (1) A clear statement of the facts and issues on which the request is based; (2) a description of the nature of any security interest in the assets of the credit union; (3) a statement of the irreparable harm likely to occur if expedited relief is not granted; (4) an assessment of the likelihood of success on the merits; (5) citations to applicable legal authority supporting the request of the merits of the claim itself; and (6) a statement certifying that a copy of the request has been mailed or hand delivered to the liquidating agent on or before the date it was filed with the Board. Under subsection (d) the party requesting expedited review has the burden of demonstrating entitlement to it.

Subsection 709.9(e) provides that the Board may request supplemental information to assist it in its decision regarding a request for expedited review. The Board may specify a date

certain for the production of the supplemental information. A failure to provide supplemental information may, at the discretion of the Board, constitute grounds for denial of the relief requested.

As stated in subsection 709.9(f), the Board must render a decision within 90 days of the date the request for expedited relief was filed. If expedited review is granted, the Board's decision will allow or disallow the claim, in whole or in part. If the claim is disallowed in whole or in part, the decision will state the reasons for the disallowance and the procedure for judicial review. If expedited review is not granted, the claim is decided pursuant to the normal claims process set forth in § 709.6. A Board decision to deny expedited review is final.

Subsections (g) and (h) apply in two situations: (1) Where the Board grants expedited review and disallows all or part of the claim; and (2) the Board fails to render any decision on the request for expedited review within 90 days of the date on which the request was filed. In either case, the claimant may seek judicial determination of its rights, with respect to its security interest, by filing a suit or continuing a suit which was filed before the appointment of the liquidating agent. Any suit must be filed or renewed within 30 days after the claimant's right to sue becomes effective under one or two above. Failure to file suit within this period shall be deemed final disallowance of the claim. Claimant shall have no further rights or remedies with respect to the claim.

#### D. Corrections

A typographical error was made in § 709.5(b)(6) when the word "unsecured" was used instead of the word "uninsured". This has been corrected.

The term "permanent capital base instruments of corporate credit unions" in § 709.5(b)(7) has been corrected to read "membership capital share deposits of corporate credit unions" for consistency with NCUA's proposed part 704—Corporate Credit Unions.

#### Regulatory Requirements

##### *Regulatory Flexibility Act*

The NCUA Board has determined and certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small credit unions (primarily those under \$1 million in assets.) It would not impose an additional burden on credit unions. Accordingly, the Board has determined that a Regulatory Flexibility Analysis is not required.



**Paperwork Reduction Act**

The Board has determined that the requirements of the Paperwork Reduction Act do not apply.

**Executive Order 12612**

The NCUA Board, pursuant to Executive Order 12612, has determined that this rule will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

**List of Subjects in 12 CFR Part 709**

Claims, Credit unions, Liquidation.

By the National Credit Union Administration Board on October 17, 1991.

Becky Baker,

Secretary of the Board.

For the reasons set forth in the preamble, a new part 709 is added to title 12, chapter VII of the Code of Federal Regulations to read as follows:

**PART 709—INVOLUNTARY LIQUIDATION OF FEDERAL CREDIT UNIONS AND ADJUDICATION OF CREDITOR CLAIMS INVOLVING FEDERALLY INSURED CREDIT UNIONS IN LIQUIDATION**

Sec.

709.0 Scope.

709.1 Definitions.

709.2 NCUA Board as liquidating agent.

709.3 Challenge to revocation of charter and involuntary liquidation.

709.4 Powers and duties of liquidating agent.

709.5 Payout priorities in involuntary liquidation.

709.6 Initial determination of creditor claims by the liquidating agent.

709.7 Procedures for appeal of initial determination.

709.8 Administrative appeal of the initial determination.

709.9 Expedited determination of creditor claims.

**Authority:** 12 U.S.C. 1766; Pub. L. 101-73, 103 Stat. 183, 530 (1989) (12 U.S.C. 1787 et seq.).

**§ 709.0 Scope.**

The rules and procedures set forth in this part apply to charter revocations of Federal credit unions pursuant to 12 U.S.C. 1787(a)(1) (A), (B) and the involuntary liquidation and adjudication of creditor claims in all cases involving federally insured credit unions. Section 709.3 applies only to Federal credit unions. Remaining sections of this Part are applicable to all federally insured credit unions. This Part does not apply to share insurance claims arising out of the liquidation of a federally insured credit union. Insurance claims are

decided pursuant to part 745 of this chapter.

**§ 709.1 Definitions.**

For the purposes of this part, the following definitions apply:

(a) *General Counsel* means the General Counsel of the National Credit Union Administration or any attorney assigned to the General Counsel's staff.

(b) *Liquidating Agent* means the NCUA Board or person(s) appointed by it with delegated authority to carry out the liquidation of the credit union.

(c) *Insolvent* means insolvency as that term is defined in § 700.1(j) of this chapter.

(d) *Claim* means a creditor's claim against the credit union in liquidation. This term does not include insurance claims arising out of the liquidation of a federally insured credit union. Insurance claims are decided pursuant to part 745 of this chapter.

(e) *Shareholder* means members, nonmembers, accountholders or any other party or entity that is the owner of a share, share certificate or share draft account or the equivalent of such accounts under state law.

**§ 709.2 NCUA Board as liquidating agent.**

(a) The Board, as liquidating agent, by operation of law and without any conveyance or other instrument, act or deed, shall succeed to all the rights, titles, powers, and privileges of the credit union, and of its shareholders, officers, and directors, with respect to the credit union and its assets, and such shareholders, officers, or directors, shall not thereafter have or exercise any such rights, powers, or privileges or act in connection with any assets or property of any nature of the credit union.

(b) The Board, as liquidating agent, shall take possession of and title to books, records, and assets of every description of such credit union to which such credit union has rights of possession and title to all offices and other facilities of such credit union.

**§ 709.3 Challenge to revocation of charter and involuntary liquidation.**

If a Federal credit union is determined to be insolvent and placed into liquidation pursuant to 12 U.S.C. 1787, the Federal credit union may, not later than 10 days after the date on which the Board closes the credit union for liquidation, apply to the United States District Court for the Judicial district in which the principal office of the credit union is located or the United States District Court for the District of Columbia for an order requiring the Board to show cause why it should not be prohibited from continuing such

liquidation. Notwithstanding other provisions of this part, the board of directors of the credit union may meet following the placing of the institution into liquidation for the sole purpose of considering and authorizing the filing of this action in the name of the credit union. No such action in the name of the credit union may be instituted without the authorization of the board of directors of the institution pursuant to a valid board of directors resolution. No credit union funds shall be available to pay expenses incurred in bringing a legal action to challenge the Board's liquidation action.

**§ 709.4 Powers and duties of liquidating agent.**

(a) *Inventory of assets.* As soon as practicable after taking possession, the liquidating agent shall inventory the assets of such credit union as of the date of taking possession, showing the value as carried on the books of the credit union, and the security therefor, if any, a brief description of the assets and any security, and a record of the credit union's creditor and accounts liabilities.

(b) *Notice to creditors.* The liquidating agent shall promptly publish a notice to the credit union's creditors to present their claims, together with proof, to the liquidating agent by a date specified in the notice. This date shall be not less than 90 days after the publication of the notice. The liquidating agent shall republish such notice approximately one and two months, respectively, after the initial publication. At the time of initial publication, the liquidating agent shall mail a notice similar to the published notice to any creditor shown on the credit union's books at the last address appearing therein. If the liquidating agent discovers the name of a creditor whose name does not appear on the credit union's books, a notice similar to the published notice shall be mailed to such creditor within 30 days after the discovery of the name and address.

(c) *General.* The liquidating agent shall collect all obligations and money due such credit union and may, to the extent consistent with its appointment, do all things desirable or expedient in its discretion to wind up the affairs of the credit union including, but not limited to, the following:

(1) Exercise all rights and powers of the credit union including, but not limited to, any rights and powers under any mortgage, deed of trust, chose in action, option, collateral note, contract, judgment or decree, or instrument of any nature;

(2) Institute, prosecute, maintain, defend, intervene, and otherwise



participate in any and all actions, suits, or other legal proceedings by and against the liquidating agent or the credit union or in which the liquidating agent, the credit union, or its creditors or shareholders, or any of them, shall have an interest, and in every way to represent the credit union, its shareholders and creditors, subject to the direction of General Counsel;

(3) Employ on a salary or fee basis such persons as in the judgment of the liquidating agent are necessary or desirable to carry out its responsibilities and functions, including, but not limited to, appraisers and Certified Public Accountants, and pay the costs out of the assets of the liquidated credit union;

(4) Employ or retain any attorney or attorneys designated by, or acceptable to, the General Counsel in connection with litigation or for legal advice and assistance, for the liquidation generally or in particular instances, and pay compensation and retainers of such attorney or attorneys, together with all expenses, including, but not limited to, the costs and expenses of any litigation, as approved by the General Counsel, out of the assets of the liquidated credit union;

(5) Execute, acknowledge, and deliver any and all deeds, contracts, leases, assignments, bills of sale, releases, extensions, satisfactions, and other instruments necessary or proper for any purposes, including, but not limited to, the effectuation, termination, or transfer of real, personal or mixed property, or that shall be necessary or proper to liquidate the credit union, and any deed or other instrument executed pursuant to the authority hereby given shall be as valid and effective for all purposes as if the same had been executed as the act and deed of the credit union;

(6) With concurrence of General Counsel, disaffirm or repudiate any contract or lease to which the credit union is a party, the performance of which the liquidating agent, in his sole discretion, determines to be burdensome, and which disaffirmance or repudiation in the liquidating agent's sole discretion will promote the orderly administration of the credit union's affairs;

(7) Deposit, withdraw, or transfer funds, and otherwise exercise complete control over all investment or depository accounts maintained by or for the credit union at financial dispository or similar institutions;

(8) Do such things, and have such rights, powers, privileges, immunities, and duties, whether or not otherwise granted in this part 709, as shall be authorized, directed, conferred, or imposed from time to time by the Board,

or as shall be conferred by the Federal Credit Union Act;

(9) Exercise such other authority as is conferred by the Federal Credit Union Act; and

(10) Where acting as liquidating agent for a state-chartered federally insured credit union, exercise all the rights, powers, and privileges granted by state law to such a liquidating agent.

(d) *Expenditure of funds of the liquidation.* The liquidating agent shall have power to:

(1) Pay all costs and expenses of the liquidation as determined by the liquidating agent;

(2) Pay off and discharge taxes and liens;

(3) Pay out and expend such sums as are deemed necessary or advisable for or in connection with the preservation, maintenance, conservation, protection, remodeling, repair, rehabilitation, or improvement of any asset or property of any nature of the credit union or the liquidating agent;

(4) Pay off and discharge any assessments, liens, claims, or charges of any kind against any asset or property of any nature on which the credit union or the liquidating agent has a lien by way of mortgage, deed of trust, pledge, or otherwise, or in which the credit union or liquidating agent has any interest;

(5) Settle, compromise, or obtain the release of, for cash or other consideration, claims and demands against the credit union or the liquidating agent; and

(6) Indemnify its employees and agents from the assets of the credit union against liabilities incurred in the good faith performance of their duties.

(e) *Assets, claims, and contracts.* The liquidating agent shall have power to:

(1) Sell for cash or on terms, exchange, assign, or otherwise dispose of, in whole or in part, any or all of the assets and property of the credit union, real, personal and mixed, tangible and intangible, of any nature, including any mortgage, deed of trust, chose in action, bond, note, contract, judgment, or decree, share or certificate of share of stock or debt, owing to the credit union or the liquidating agent; and

(2) Surrender, abandon, and release any chose in action, or other assets or property of any nature, whether the subject of pending litigation or not, and settle, compromise, modify, or release, for cash or other consideration, claims and demands in favor of the credit union or the liquidating agent.

#### § 709.5 Payout priorities in involuntary liquidation.

(a) Claimants whose claims are secured shall receive their security. To the extent their respective claims exceed the value of the security for those claims, as determined to the satisfaction of the liquidating agent, they shall each have an unsecured claim against the credit union having priority as provided in paragraph (b) of this section.

(b) Unsecured claims against the liquidation estate that are proved to the satisfaction of the liquidating agent shall have priority in the following order:

(1) Administrative costs and expenses of liquidation;

(2) Claims for wages and salaries, including vacation, severance, and sick leave pay;

(3) Taxes legally due and owing to the United States or any state or subdivision thereof;

(4) Debts due and owing the United States, including the National Credit Union Administration;

(5) General creditors, and secured creditors (to the extent that their respective claims exceed the value of the security for those claims);

(6) Shareholders to the extent of their respective uninsured shares and the National Credit Union Share Insurance Fund to the extent of its payment of share insurance; and

(7) In a case involving liquidation of a corporate credit union, membership capital share deposits of corporate credit unions.

(c) Priorities are to be based on the circumstances that exist on the date of liquidation.

(d) If the repudiation or disaffirmance of any contract or lease gives rise to a claim for damages, such claim shall be considered a general creditor claim under paragraph (b)(5) of this section and not a cost or expense of liquidation under paragraph (b)(1) of this section.

(e) All unsecured claims of any category or class or priority described in paragraphs (b)(1) through (b)(7) of this section shall be paid in full, or provisions made for such payment, before any claims of lesser priority are paid. If there are insufficient funds to pay all claims of a category or class, payment shall be made pro rata. Notwithstanding anything to the contrary herein, the liquidating agent may, at any time, and from time to time, prior to the payment in full of all claims of a category or class with higher priority, make such distributions to claimants in priority categories described in paragraphs (b)(1), (b)(2), (b)(3), (b)(4), and (b)(5) of this section as



the liquidating agent believes are reasonably necessary to conduct the liquidation, provided that the liquidating agent determines that adequate funds exist or will be recovered during the liquidation to pay in full all claims of any higher priority. If a surplus remains after making distribution in full on all allowed claims described in paragraphs (b)(1) through (b)(7) of this section, such surplus shall be distributed pro rata to the credit union's shareholders.

**§ 709.6 Initial determination of creditor claims by the liquidating agent.**

(a)(1) Any party wishing to submit a claim against the liquidated credit union must submit a written proof of claim in accordance with the requirements set forth in the notice to creditors. A failure to submit a written claim within the time provided in the notice to creditors shall be deemed a waiver of said claim and claimant shall have no further rights or remedies with respect to such claim.

(2) Notwithstanding paragraph (a)(1) of this section, the liquidating agent may, at his discretion, consider an untimely claim provide the following two criteria are present:

(i) The claimant did not receive notice of the appointment of the liquidating agent in time to file a claim before the date provided for in the notice; and

(ii) The claim is filed in time to permit payment of the claim.

(b) The liquidating agent may require submission of supplemental evidence by the claimant and by interested parties in the event of a dispute concerning a claim against any asset of the liquidated credit union. In requiring the submission of supplemental evidence, the liquidating agent may set such limitations of time, scope, and size as the liquidating agent deems reasonable in the circumstances, and may refuse to include in the record submissions or portions of submissions not in compliance with such limitations or requirements. The liquidating agent shall compile such written record of a claim or dispute as, in its discretion, is deemed sufficient to provide a reasonable basis for allowing or disallowing a claim or resolving a dispute. This written record shall be considered the administrative record.

(c) The liquidating agent shall determine whether to allow or disallow a claim and shall notify the claimant within 180 days from the date a claim against a credit union is filed pursuant to paragraph (a)(1) of the section. This 180-day period may be extended by written agreement between the claimant and the liquidating agent. Failure by the liquidating agent to determine a claim and notify the claimant within the 180-

day period or, if the period is extended, within the extended period, shall be deemed a denial of the claim.

(d) If a claim or any portion thereof is disallowed, the notice to the claimant shall contain a statement of the reasons for the disallowance and an explanation of appeal rights pursuant to § 709.7 of this part.

(e) Notice of any determination with respect to a claim shall be sufficient if mailed to the most recent address of the claimant which appears:

(1) On the credit union's books;

(2) In the claim filed by the claimant; or

(3) In the documents submitted in the proof of claim.

(f) In the event the liquidating agent disallows all or part of a claim, the liquidating agent shall file with the Board, or its designated agent, a report of its determination. This report shall become part of the record and shall include the notice to the claimant and findings on all issues raised and decided by the liquidating agent.

**§ 709.7 Procedures for appeal of initial determination.**

In order to appeal all or part of an initial decision which disallows a claim, in whole or in part, a claimant must, within 60 days of the mailing of the initial determination, file an administrative appeal pursuant to § 709.8 of this part, or file suit against the liquidated credit union in the United States District Court for the District of Columbia or in the United States district court having jurisdiction over the place where the credit union's principal place of business is located, or continue an action commenced before the appointment of the liquidating agent. If the claimant does not appeal or file or continue a suit, any disallowance shall be final and the claimant shall have no further rights or remedies with respect to such claim.

**§ 709.8 Administrative appeal of the initial determination.**

(a) *General.* A claimant requesting an administrative appeal may request review pursuant to any of the procedures listed in paragraphs (b) or (c) of this section. Any appeal of the initial determination must be in writing and must specify what type of appeal the claimant requests. The determination of whether to agree to a request for administrative appeal shall rest solely with the Board, which shall notify the claimant of its decision in writing. The 60 day period for filing a lawsuit in United States district court, provided for in § 709.7 of this part, shall be tolled from the date of claimant's request for

an administrative appeal to the date of the Board's decision regarding that request.

(b) *Hearing on the record.* Except as provided herein, any hearing requested pursuant to this section shall be conducted in accordance with the provisions of subpart A, part 747, of this chapter. The Board shall render a final decision with respect to such claim after consideration of the hearing record and recommended decision. The Board's determination shall be subject to judicial review under chapter 7 of title 5, United States Code. Any claimant seeking judicial review of the Board's final decision under this paragraph must file a petition in the court of appeals for the circuit in which the principal office of the credit union is located, or in the United States Court of Appeals for the District of Columbia Circuit, within 30 days of the date of the Board's final decision. If a claimant does not file a petition before the end of the 30-day period, the Board's decision shall be final, and the claimant shall have no further rights or remedies with respect to such claim.

(1) *Burden of proof.* In any hearing on the record, the burden of proof to establish entitlement to any modification of the initial determination shall rest solely upon the claimant.

(2) *Order of procedure.* In any hearing on the record, at the time for opening arguments, counsel for the claimant shall argue first, and at the time for closing arguments, counsel for the claimant shall argue last.

(c) *Alternative dispute resolution.* Paragraphs (c) (1) and (2) of this section list alternatives for dispute resolution which may be available at the discretion of the Board. From time to time, the NCUA Board may authorize additional alternative dispute resolution processes.

(1) *Appeal to the Board.* Pursuant to this paragraph (c)(1), the claimant may file an appeal with the NCUA Board within the time provided for in § 709.7. The appeal must be in writing and filed with the Secretary of the Board, National Credit Union Administration, 1776 G Street NW., Washington, DC 20456. There shall be no personal appearance before the Board in connection with an appeal under this paragraph (c)(1).

(i) *Content of appeal.* Any appeal must include:

(A) A statement of the facts on which the appeal is based;

(B) A statement of the basis for the initial determination to which the claimant objects and the alleged error in



such determination, including citations to applicable statutes and regulations;

(C) Any other evidence relied upon by the claimant which was not previously provided to the liquidating agent.

(ii) *Procedures for review of the appeal.* (A) Within 60 days of the date of the Board's receipt of an appeal, pursuant to paragraph (c)(1) of this section, the Board may request in writing that the claimant submit supplemental evidence in support of its appeal. If additional evidence is requested, the claimant shall have 45 days from the date of issuance of such request to provide such additional information. Failure by the claimant to provide such additional information may, as determined solely by the Board, result in denial of the claimant's appeal.

(B) Within 60 days from the date of the Board's receipt of an appeal, pursuant to paragraph (c)(1) of this section, the claimant may amend or supplement the appeal in writing. In the event the claimant does amend or supplement the appeal, the provisions of paragraph (c)(1)(ii)(A) of this section, with respect to requests for additional information and responses to such requests, shall apply with equal force to any such amendment or supplement to an appeal.

(iii) *Determination on appeal.* (A) Within 180 days from the date of receipt of an appeal by the Board, the Board shall issue a decision allowing or disallowing claimant's appeal.

(B) The decision by the Board on appeal shall be provided to the claimant in writing, stating the reasons for the decision, and shall constitute a final agency decision regarding the claimant's claim.

(C) Failure by the Board to issue a decision on appeal of the claimant's claim within the 180-day period provided for under paragraph (c)(1)(iii)(A) of this section shall be deemed to be a denial of such appeal for the purposes of paragraph (c)(1)(iv) of this section.

(iv) *Judicial review.* (A) For the purposes of seeking judicial review of actions taken pursuant to paragraph (c)(1) of this section, only a determination on appeal issued by the NCUA Board pursuant to this Section shall constitute a final determination regarding a claim.

(B) A final determination by the Board is reviewable in accordance with the provisions of chapter 7, title 5, United States Code, by the United States Court of Appeals for the District of Columbia or the court of appeals for the Federal judicial circuit where the credit union's principal place of business is located. Any request for judicial review under

this subparagraph must be filed within 60 days of the date of the Board's final decision. If any claimant fails to file before the end of the 60-day period, the Board's decision shall be final, and the claimant shall have no further rights or remedies with respect to such claim.

(2) The following additional procedures for dispute resolution may be made available at the sole discretion of the Board: mediation; nonbinding arbitration; and neutral fact finding.

#### **§ 709.9 Expedited determination of creditor claims.**

(a) *General.* The provisions of this section establish procedures under which claimants may request expedited relief in lieu of the procedures set forth in § 709.6 of this part. A claimant shall be entitled to expedited determination of a claim only upon a showing that there exists a legally valid and enforceable or perfected security interest in assets of the liquidated credit union and that irreparable injury will occur if the routine claims procedure is followed.

(b) *Filing of request for expedited relief.* All requests for expedited relief must be filed within 30 days from the date of mailing, by the liquidating agent, of the notice to the creditor concerned. The request shall be deemed to be filed when received by the Secretary of the Board, National Credit Union Administration, 1776 G Street NW., Washington, DC 20456. A copy of the request must be simultaneously served upon the liquidating agent for the credit union concerned. There shall be no right of personal appearance before the Board in connection with any claim submitted under this paragraph.

(c) *Content of request for expedited relief.* Any Request for Expedited Relief must contain the following:

(1) A clear and concise statement of the facts and issues on which the request is based;

(2) A clear and concise statement describing the nature of any security interests in any assets of the credit union;

(3) A clear and concise statement of the probable, imminent and irreparable harm likely to occur if expedited relief is not granted;

(4) An assessment of the likelihood of success on the merits of the underlying claim, including statutory citations and relevant documentation supporting the merits of the claim;

(5) Any other relevant documentation that supports the request;

(6) Citations to applicable statutes, regulations, or other legal authority; and

(7) A signed statement certifying that a copy of the request has been mailed or

hand delivered to the liquidating agent on or before the day that the request was filed with the Board.

(d) *Burden of proof.* The burden of proving entitlement to expedited relief rests at all times with the requester.

(e) *Additional information.* The Board may order the filing of additional information and or documentation in order to make its determination. Such filing shall be on a date certain, and failure to provide the additional documentation or information may constitute the sole grounds for denial of the request.

(f) *Decision.* Before the end of the 90-day period beginning on the date a request is filed, the Board shall render its decision and provide it to the requester. The Board will determine whether to grant expedited review and allow or disallow the claim or whether such claim should be resolved pursuant to the claims process described in § 709.6 of this part.

(1) *Expedited review denied.* A decision by the Board that expedited review is not appropriate shall be final and the claim shall be decided pursuant to the claims adjudication process set forth in § 709.6 of this part.

(2) *Expedited review granted.* If expedited review is granted, the Board shall decide the claim. If the claim is disallowed, in whole or part, the decision shall contain a statement of each reason for the disallowance and the procedure for obtaining judicial review.

(g) *Period for filing or renewing suit.* Any claimant who files a request for expedited relief shall be permitted to file a suit, or to continue a suit filed before the appointment of the liquidating agent, seeking a determination of the claimant's rights with respect to its security interest after the earlier of:

(1) The end of the 90-day period beginning on the date of the filing of a request for expedited relief; or

(2) The date the Board denies all or part of the claim.

(h) *Statute of limitations.* If an action described in paragraph (g) of this section is not filed, or the motion to renew a previously filed suit is not made, before the end of the 30-day period beginning on the date on which such action or motion may be filed in accordance with paragraph (g) of this section, the claim shall be deemed to be disallowed as of the end of such period (other than any portion of such claim that was allowed by the Board). Such disallowance shall be final and the



claimant shall have no further rights or remedies with respect to such claim.

[FR Doc. 91-26071 Filed 11-6-91; 8:45 am]

BILLING CODE 7535-01-M

## FEDERAL HOUSING FINANCE BOARD

### 12 CFR Part 932

[No. 91-559]

#### Eligibility and Financial Disclosure Requirements for Directors of the Federal Home Loan Banks

**AGENCY:** Federal Housing Finance Board.

**ACTION:** Final rule; information collection approval.

**SUMMARY:** The Federal Housing Finance Board ("Finance Board") is amending its final rule on eligibility, financial disclosure and conflict of interest

requirements for directors of the Federal Home Loan Banks ("FHLBanks"), which was published at 56 FR 55205 (October 25, 1991), to include the assigned Office of Management and Budget ("OMB") control number in the regulatory text.

**EFFECTIVE DATE:** November 25, 1991.

#### FOR FURTHER INFORMATION CONTACT:

Sharon B. Like, Attorney/Advisor, Office of the General Counsel, (202) 408-2930, Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006.

**SUPPLEMENTARY INFORMATION:** On October 25, 1991, the Finance Board published a final rule under 12 CFR part 932 on eligibility, financial disclosure and conflict of interest requirements for directors of the FHLBanks (56 FR 55205). OMB has approved the information collection requirements contained in §§ 932.18(f) (1) through (3) and (g)(1), 932.21(g) (1) through (3), and 932.23 of

the final rule pursuant to the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35, and has assigned these collections OMB control number 3069-0002, expiration date October 31, 1994.

Under OMB's regulations implementing the Paperwork Reduction Act, agency regulations containing information collection requirements that are published in the Federal Register also must publish the OMB control number as part of the regulatory text or as a technical amendment. 5 CFR 1320.7(e)(2). This document of the Finance Board amends the applicable sections of the Finance Board's final director eligibility rule to include the assigned OMB control number in the regulatory text.

In accordance with 5 CFR 1320.21 of OMB's regulations, the following table discloses the estimated annual reporting burden for each collection of information in the final rule:

#### ESTIMATED ANNUAL REPORTING BURDEN

Description of information collection	Avg. No. of respondents	×	Avg. No. of responses per respondent	=	Total avg. responses	×	Wtd. avg. <sup>1</sup> minutes per response	=	Total wtd. avg. hours
1. A-1 Appointive Director Candidates—Personal Certification and Disclosure Form	120		1		120		<sup>2</sup> 50		100
2. A-2 Appointive Directors—Personal Certification and Disclosure Form	48		1		48		60		48
3. E-1 Elective Director Nominees—Personal Certification and Disclosure Form	180		1		180		<sup>3</sup> 40		120
4. E-2 Elective Directors—Personal Certification and Disclosure Form	60		1		60		60		60
Totals	408		1		408		<sup>4</sup> 50		<sup>5</sup> 328

<sup>1</sup> Assumes an average of 60 minutes to complete all sections of the Form. "Wtd." = weighted.

<sup>2</sup> ((72 finalists × 60 minutes) + (48 candidates not selected × 30 minutes)) / 120 total appointive director candidates = 48 minutes (rounded to 50 minutes).

<sup>3</sup> ((60 finalists × 60 minutes) + (120 nominees not elected × 30 minutes)) / 180 total elective director nominees = 40 minutes.

<sup>4</sup> Rounded from 48 minutes.

<sup>5</sup> This number was estimated originally at 394 hours in the Finance Board's Paperwork Reduction Act Analysis in its proposed rules (56 FR 37303 (Aug. 6, 1991)). However, further analysis of the reporting burden indicated that the initial Analysis had overestimated the total burden to respondents. The revised estimate of 328 hours was subsequently submitted to OMB for clearance under the Paperwork Reduction Act.

Any comments on this information collection should be sent to the Office of Information and Regulatory Affairs, OMB, Attention: Gary Waxman, room 3201, New Executive Office Building, Washington, DC 20503; with copies to the Executive Secretary, Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006.

#### List of Subjects in 12 CFR Part 932

Conflict of interests, Federal home loan banks, Reporting and recordkeeping requirements.

Accordingly, title 12, chapter IX, subchapter B of the Code of Federal Regulations is amended as follows:

#### PART 932—ORGANIZATION OF THE BANKS

1. The authority citation for part 932 continues to read as follows:

Authority: Secs. 2A, 2B, as added by sec. 702, 103 Stat. 413, 414 (12 U.S.C. 1422a, 1422b); secs. 6-7, 47 Stat. 727, 730, as amended by secs. 707, 710(b)(4), 103 Stat. 417, 418 (12 U.S.C. 1426-1427); sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); sec. 207, 62 Stat. 692, as added by sec. 1a, 76 Stat. 1123, as amended (18 U.S.C. 207); sec. 602, 92 Stat. 2115, as amended (42 U.S.C. 8101, *et seq.*).

§§ 932.18, 932.21, 932.23 [Amended]

2. Sections 932.18, 932.21 and 932.23 are amended by adding the parenthetical "(Approved by the Office of Management and Budget under control number 3069-0002)" at the end of each section.

Dated: October 31, 1991.

By the Federal Housing Finance Board.

J. Stephen Britt,

Executive Director.

[FR Doc. 91-26825 Filed 11-6-91; 8:45 am]

BILLING CODE 6725-01-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 91-ANE-38; Amendment 39-8082; AD91-23-13]

#### Airworthiness Directives; General Electric Company (GE) CF6-50 Series and CF6-80A Series Turbofan Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.



**ACTION:** Final rule, request for comments.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to GE CF6-50 series and CF6-80A series turbofan engines, which requires removal from service of certain stage 1 fan disks which may have metallurgical defects. This amendment is prompted by reports of the existence of a metallurgical defect in a CF6-80A stage 1 fan disk which adversely affects the service life of the disk. This condition, if not corrected, could result in an uncontained engine failure and damage to the aircraft.

**DATES:** Effective November 22, 1991.

Comments must be received no later than December 9, 1991.

**ADDRESSES:** Send comments in duplicate to the FAA, New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91-ANE-38, 12 New England Executive Park, Burlington, Massachusetts 01803-5299, or deliver in duplicate to room 311 at the above address.

Comments may be inspected at the above location between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Karen M. Grant, Engine Certification Office, ANE-140, Engine and Propeller Directorate, Aircraft Certification Service, FAA, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803-5299; telephone (617) 273-7096.

**SUPPLEMENTARY INFORMATION:** A subsurface ultrasonic inspection of a stage 1 fan disk in a CF6-80A turbofan engine revealed a low density Type 1 hard alpha inclusion. The inclusion was located in the tapered transition area between the disk web and rim. Other disks produced from the same heat lot of material have a high probability of metallurgical defects which could propagate to failure prior to the fan disk reaching its life limit. This condition, if not corrected, could result in an uncontained engine failure and damage to the aircraft.

Since this situation is likely to exist or develop on other engines of this same type design, this AD requires the removal from service of all affected stage 1 fan disks.

Since a situation exists that may result in an uncontained engine failure and damage to the aircraft, there is a need to minimize the exposure of revenue service aircraft to operation with metallurgically defective stage 1 fan disks. Based on this condition, a

situation exists that requires the immediate adoption of this regulation. Therefore, it is found that notice and public procedure here on are impracticable, and good cause exists for making this amendment effective in less than 30 days.

Although this action is in the form of a final rule, which involves an emergency, and thus was not preceded by notice and public procedure, interested persons are invited to submit such written data, views, or arguments as they may desire regarding this AD. Communications should identify the docket number and be submitted to the FAA, New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91-ANE-38, 12 New England Executive Park, Burlington, Massachusetts 01803-5299. All communications received by the deadline date indicated above will be considered by the Administrator, and the AD may be changed in light of the comments received. The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Executive Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket (otherwise, an evaluation is not required). A copy of it may be obtained from the Rules Docket.

#### List of Subjects in 14 CFR part 39

Air transportation, Aircraft, Aviation safety, and Safety.

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator,

the Federal Aviation Administration (FAA) amends 14 CFR part 39 of the Federal Aviation Regulations (FAR) as follows:

#### PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

#### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive (AD):

**91-23-13 General Electric Company:**  
Amendment No. 39-8082. Docket No. 91-ANE-38.

**Applicability:** General Electric Company (GE) CF6-50 series and CF6-80A series turbofan engines, installed on, but not limited to, Airbus A300 and A310, Boeing 747 and 767, and McDonnell Douglas DC10-15 and DC10-30 aircraft.

**Compliance:** Required as indicated, unless previously accomplished.

To prevent an uncontained engine failure and damage to the aircraft, accomplish the following:

(a) Within 30 days after the effective date of this AD, remove from service stage 1 fan disks identified by the following part number (P/N) and serial number (S/N):

Engine Model	Part Number	Serial Number
CF6-50	9253M66P02	MPON2919
	9253M66P02	MPON2920
	9253M66P02	MPON2921
	9253M66P02	MPON2922
CF6-80A	9319M28P03	MPON4290
	1327M57P02	MPON4291
	9319M28P02	MPON4292
	9319M28P03	MPON7740
	9319M28P03	MPON7742
	9319M28P03	MPON8452
	9319M28P03	MPON8453

Prior to returning affected engines to service replace with a serviceable part.

(b) Aircraft may be ferried in accordance with the provisions of FAR 21.197 and 21.199 to a base where the AD can be accomplished.

(c) Upon submission of substantiating data by an owner or operator through an FAA Inspector (maintenance, avionics, or operations, as appropriate), an alternate method of compliance with the requirements of this AD or adjustments to the compliance times specified in this AD may be approved by the Manager, Engine Certification Office, Engine and Propeller Directorate, Aircraft Certification Service, 12 New England Executive Park, Burlington, Massachusetts 01803-5299.

This amendment (39-8082, AD 91-23-13) becomes effective November 22, 1991.



Issued in Burlington, Massachusetts, on October 22, 1991.

Jack A. Sain,

Manager, Engine and Propeller Directorate,  
Aircraft Certification Service.

[FR Doc. 91-26867 Filed 11-6-91; 8:45 am]

BILLING CODE 4910-13-M

## 14 CFR Part 71

[Airspace Docket No. 91-AEA-01]

### Alteration of Transition Area and Establishment of Control Zone; Manassas, VA

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This notice modifies the Chantilly, VA, 700 foot Transition Area and establishes a Control Zone at the Manassas Municipal/Harry P. Davis Airport, Manassas, VA. This action is deemed necessary due to a review of air traffic control procedures in the area and the establishment of an FAA-operated Air Traffic Control Tower (ATCT) at the airport. This notice incorporates minor corrections and changes to the mileages and bearings previously published in the Federal Register (56 FR 6591).

**EFFECTIVE DATE:** 0901 U.T.C., January 9, 1992.

#### FOR FURTHER INFORMATION CONTACT:

Mr. Curtis L. Brewington, Airspace Specialist, System Management Branch, AEA-530, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone: (718) 553-0857.

#### SUPPLEMENTARY INFORMATION:

##### History

On February 4, 1991, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Chantilly, VA, 700 foot Transition Area and establish a Control Zone at Manassas, VA (56 FR 6591). The proposed action would increase the amount of controlled airspace in the area to segregate aircraft operating under instrument procedures from other aircraft operating under visual weather conditions in controlled airspace.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments on the proposal were received. Except for editorial changes, this amendment is the same as that proposed in the notice. Sections 71.171 and 71.181 of part 71 of the Federal

Aviation Regulations were republished in FAA Handbook 7400.6G, September 4, 1990.

#### The Rule

This amendment to part 71 of the Federal Aviation Regulations revises a portion of the Chantilly, VA, 700 foot Transition Area and establishes a Control Zone at Manassas, VA, due to a review of air traffic control procedures in the area and the establishment of an FAA-operated ATCT at the Manassas Municipal/Harry P. Davis Airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 71

Aviation safety, Control zones, Transition areas.

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 71 of the Federal Aviation Regulations (14 CFR part 71) is amended as follows:

#### PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. App. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

#### § 71.171 [Amended]

2. Section 71.171 is amended as follows:

##### Manassas, VA [New]

Manassas Municipal/Harry P. Davis Airport, Manassas, VA (lat. 38°43'17"N., long. 77°30'57"W.).

Within a 4.7-mile radius of the center of the Manassas Municipal/Harry P. Davis Airport, Manassas, VA and within 2.9 miles either side of a 025°(T) 035°(M) bearing extending from the airport to 8.6 miles northeast of the airport. This Control Zone is effective during

the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

#### § 71.181 [Amended]

3. Section 71.181 is amended as follows:

##### Chantilly, VA [Amended]

Replace the following:

"within a 6.5-mile radius of the center, lat. 38°43'17"N., long. 77°30'57"W., of Manassas Municipal Airport (Harry P. Davis Field), Manassas, VA, within 2.5 miles each side of a 330° bearing from a point at lat. 38°43'36"N., long. 77°31'17"W., extending from said point to 9.5 miles northwest"

to read as follows:

"within a 7.6-mile radius of the center of the Manassas Municipal/Harry P. Davis Airport (lat. 38°43'17"N., long. 77°30'57"W.), Manassas, VA and within 2.9 miles either side of a 025°(T) 035°(M) bearing extending from the airport to 8.6 miles northeast of the airport and within 2.3 miles either side of a 326°(T) 336°(M) bearing from a point located at lat. 38°43'36"N., long. 77°31'27"W., extending from said point to 9.3 miles northwest; excluding that portion which coincides with Restricted Area R-6608A."

Issued in Jamaica, New York, on October 21, 1991.

Gary W. Tucker,

Manager, Air Traffic Division.

[FR Doc. 91-26868 Filed 11-6-91; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF THE TREASURY

### Fiscal Service

#### 31 CFR Part 211

#### Delivery of Checks and Warrants to Addresses Outside the United States, Its Territories and Possessions

**AGENCY:** Financial Management Service, Fiscal Service, Treasury.

**ACTION:** Final rule; amendment.

**SUMMARY:** This final rule amends the regulations governing the delivery of checks outside the United States by removing the reference to the former German Democratic Republic and the Soviet Sector of Berlin. The German Democratic Republic, the Soviet Sector of Berlin and the Federal Republic of Germany were officially unified on October 3, 1990. There is reasonable assurance that payees living in the unified Germany will receive checks or warrants drawn against funds of the United States, its agencies or instrumentalities thereof, and will be able to negotiate the same for full value.

**EFFECTIVE DATE:** November 7, 1991.



**FOR FURTHER INFORMATION CONTACT:** Anthony R. Torrice, Director, Product Integrity Division, Financial Management Service, Department of the Treasury, Washington, DC 20227, (202) 874-6810.

**SUPPLEMENTARY INFORMATION:** The German Democratic Republic, the Soviet Sector of Berlin and the Federal Republic of Germany were officially unified on October 3, 1990. There is reasonable assurance that payees living in the unified Germany will receive checks or warrants drawn against funds of the United States, its agencies or instrumentalities thereof, and will be able to negotiate the same for full value. For this reason, 31 CFR 211.1(a) concerning withholding delivery of checks and warrants is being amended to delete the references to the German Democratic Republic and the Soviet Sector of Berlin. (See also 56 FR 45894 (September 9, 1991), amendments to the Treasury Transaction Control and Foreign Funds Control Regulations, to delete references to the former German Democratic Republic and East Berlin.)

Because this rule removes a restriction on the delivery of checks and warrants to a foreign country, the Department of the Treasury has determined that notice of proposed rulemaking, public procedure and a delayed effective date would be contrary to the public interest pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(1). This rule is not subject to the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because no notice of proposed rulemaking is required under 5 U.S.C. 553 or any other law.

The Department of the Treasury has determined that this is not a major regulation as defined by Executive Order 12291. Accordingly, regulatory impact analysis is not required.

#### List of Subject in 31 CFR Part 211

Foreign banking, Foreign claims.

For the reasons set out in the preamble, 31 CFR part 211 is amended as set forth below.

#### PART 211—DELIVERY OF CHECKS AND WARRANTS TO ADDRESSES OUTSIDE THE UNITED STATES, ITS TERRITORIES AND POSSESSIONS

1. The authority citation for part 211 continues to read as follows:

Authority: 31 U.S.C. 321 and 5 U.S.C. 301.

##### § 211.1 [Amended]

2. Section 211.1(a) is amended by removing the words "the Socialist Republic of Vietnam, the German Democratic Republic, and the Soviet Sector or Berlin, Germany" and adding

in their place the words "and the Socialist Republic of Vietnam".

Russell D. Morris,  
Commissioner.

[FR Doc. 91-26596 Filed 11-6-91; 8:45 am]

BILLING CODE 4810-35-M

#### DEPARTMENT OF DEFENSE

##### Office of the Secretary

##### 32 CFR Part 290

[DCAA 5410.8]

#### Defense Contract Audit Agency (DCAA); Freedom of Information Act Program

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Amendment of final rule.

**SUMMARY:** The Defense Contract Audit Agency amends its final rule which implements the Freedom of Information Act of 1974, as amended (5 U.S.C. 552). The change incorporates specific guidance on processing requests for audit working papers. It also defines audit working papers and offers information relative to the structure and development of the audit working paper files.

**DATES:** This change will be effective January 6, 1992. Comments must be received by December 9, 1991.

**ADDRESSES:** Forward comments to: Headquarters, Defense Contract Audit Agency, ATTN: CMR, Cameron Station, Alexandria, Virginia 22304-6178.

**FOR FURTHER INFORMATION CONTACT:** Mr. Dave Henshall, (703) 274-4400.

**SUPPLEMENTARY INFORMATION:** The Agency's final rule was published in the Federal Register on Tuesday, October 1, 1991 (56 FR 49685). This change provides definitive guidance on processing requests for audit working papers. Section 290.7 is amended by redesignating paragraph (d) and adding a new paragraph (c). This amendment also adds a new appendix D to this part.

#### List of Subjects in 32 CFR Part 290

Freedom of information.

#### PART 290—[AMENDED]

Accordingly 32 CFR part 290 is amended as follows:

1. The authority citation for part 290 continues to read as follows:

Authority: 5 U.S.C. 552.

2. Section 290.7 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) as follows:

#### § 290.7 Procedures.

(c) *Requests for Audit Working Papers.* Audit working papers, as described in appendix D, may be sought occasionally in conjunction with an audit report or as an independent demand. Normally, the release of such records is entirely dependent on the releasability of the related audit report. (Note: The procedures for determining the releasability of audit reports is provided in general in the aforementioned paragraph and in more detail in DCAAP 5410.14). Since the content of audit working paper files can be quite diverse and often voluminous, FOIA Coordinators should work closely with the requester to ensure that the records produced are narrowly defined and entirely responsive to the requester's needs.

Appendix D to Part 290—Audit Working Papers, is added as follows:

#### Appendix D to Part 290—Audit Working Papers

##### (a) Definition

(1) Audit working papers contain information from accounting and statistical records, personal observations, the results of interviews and inquiries, and other available sources. Audit working papers may also include contract briefs, copies of correspondence, excerpts from corporate minutes, organization charts, copies of written policies and procedures, and other substantiating documentation. The extent and arrangement of working paper files will depend to a large measure on the nature of the audit assignment.

(2) Working papers are generally classified in two categories: the permanent file and the current file.

##### (i) Permanent file.

(A) The permanent file on each contractor is a central repository of information gathered during the course of an audit which has continuing value and use to subsequent audits expected to be performed at the same contractor. Permanent files are useful in preparing the audit program and in determining the appropriate scope of subsequent audits. They also provide ready means for auditors to become familiar with the contractor's operations and any existing audit problems or contractor system weaknesses. While summary information on the contractor's organization, financial structure and policies may sometimes be included in permanent files for smaller contractors, such information on large contractors with continuing audit activity is generally maintained in the field audit office at the central reference library.

(B) Items which would logically be included in the permanent file as having continuing value in future audit assignments include:

(1) Internal control questionnaire.



(2) Internal control review update control log.

(3) Vulnerability assessment.

(4) MAARs control log.

(5) Disclosure statement and revisions in accordance with CAS rules and regulations, and

(6) CAS compliance control schedules and a noncompliance summary schedule.

(ii) Current File. The current file usually consists of working papers which have limited use on future assignments. DCAA Forms 7640-19 a, b, and c are the Agencywide Working Paper Indexes and provide a concise summary of items generally found in audit working papers.

(b) *Explanation.*

(1) The preparation of working papers assists the auditor in accomplishing the objectives of an audit assignment. Working papers serve as the basis for the conclusions in the audit report; provide a record of the work done for use as substantiating data in negotiations, appeals, and litigation; provide guidance for subsequent examinations; and serve as a basis for the review and evaluation of the work performed.

(2) Audit working papers are generally prepared at the time audit work is performed and are maintained on a current basis. Working papers normally reflect the progress of the audit and are designed to ensure continuity of the audit effort.

(3) Working papers should be relevant to the audit assignment and not include extraneous pages. Superseded working papers should be clearly marked as such and retained as part of the working paper package.

(4) The nature of audit working papers requires that proper control and adequate safeguards be maintained at all times. Working papers frequently reflect information considered confidential by the contractor and are marked "For Official Use Only" or are classified for government security purposes.

Dated: November 4, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-26907 Filed 11-6-91; 8:45 am]

BILLING CODE 3810-01-M

## POSTAL SERVICE

### 39 CFR Part 265

#### Amendment of Release of Information Regulations—Predisclosure Notification Procedures

**AGENCY:** Postal Service.

**ACTION:** Final rule.

**SUMMARY:** The rule as adopted adds a new section to the Postal Service's regulations that implement the Freedom of Information Act to prescribe the procedures to be followed in notifying submitters of business information that this information has been requested under the FOIA. The rule closely follows

the guidelines of Executive Order 12600, 52 FR 23781 (1987).

**EFFECTIVE DATE:** March 6, 1992.

**FOR FURTHER INFORMATION CONTACT:** Charles D. Hawley, Assistant General Counsel, (202) 268-2971.

**SUPPLEMENTARY INFORMATION:** The rule is substantially the same as the proposed rule published on May 17, 1989, for comment. It calls for interaction between the Postal Service and those persons who submit sensitive business information to ensure the appropriate protection of that information when it is sought under the Freedom of Information Act. The process will be initiated by the submitter who identifies any information to which he wishes the notification procedure to apply. § 265.8(e). The Postal Service then will notify the submitter if those records become the subject of a FOIA request. § 265.8(b)-(c).

The submitter will have an opportunity to object to disclosure of the information in response to that request § 265.8(f). The Postal Service will consider any objection and determine whether to comply with the FOIA request. If it determines to comply, it will notify the submitter before the disclosure date. § 265.8(h)(3). If, on the other hand, the Postal Service determines that the information is exempt, it will notify the requester, § 265.8(g), and if the requester brings suit, the submitter will be notified. § 265.8(i). Under certain circumstances, set forth in § 265.8(d), notification to the submitter will not need to be given.

The effective date of the rule is being deferred for 90 days from the date of publication of this notice to give submitters of business information sufficient time to implement the designation procedures prescribed in § 265.8(e).

#### Analysis of Comments Received

Six written comments were received. Three subsections of the proposed rule have been changed in response to these comments. A few minor modifications of an editorial nature have also been made.

As proposed, the introductory paragraph, § 265.8(a), stated, *inter alia*:

This section does not affect the Postal Service's right, authority, or obligation to disclose information in any other context, nor is it intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the Postal Service, its officers, or any person.

One commenter expressed concern that this sentence might be misconstrued to suggest that submitters have no legal rights with respect to disclosure of

information they have submitted and proposed that its language be clarified to prevent such a misconception. It is not our intention that the rule be interpreted as affecting rights otherwise provided by law. To clear up any ambiguity on this point, we have added to the paragraph the following sentence: Existing rights of submitters are also unaffected.

As proposed § 265.8(d)(5) would have provided that notification to the submitter need not be given when the submitter's designation of business information "appears obviously frivolous." A commenter objected in substance to this provision on the ground that the standard is too vague and is likely to lead to inconsistent, erroneous, and arbitrary application. While this provision appears in Executive Order 12600, we think that the objection has merit and we have deleted the provision from the final rule.

Five of the commenters represent postal customers that mail in bulk at second- and third-class rates. These commenters have specifically addressed the applicability of these procedures, and in particular of the designation requirement, to the statement of mailing (e.g., PS Form 3602) that is generally required to be submitted to the post office at the time a customer's bulk mailing is presented.

As proposed, § 265.8(e) required that the submitters of business information "designate, by appropriate markings \* \* \* those portions of their submissions which they deem to be protected from disclosure." One commenter suggested that all mailing statements be considered as though the submitter had been notified and had objected, so that designation by individual submitters would be unnecessary. Another suggested that a submitter be permitted to file a single designation covering all similar submissions, in lieu of a separate designation with each submission. Three others urged that the Postal Service adopt a categorical approach in its disclosure determinations; two of these commenters argued that all mailing statements should be treated as presumptively exempt from mandatory disclosure, and the other argued conversely that all mailing statements should be made available to the public. Under either categorical approach, the designation, notice, and objection procedures would be made unnecessary for mailing statements.

In our experience, not all mailers do in fact object to disclosure of the statements filed for their own mailings. This is supported by the last comment



noted above that favors categorical disclosure of all mailing statements. The comment was filed on behalf of two associations, each of which represents both second- and third-class mailers. Nor do all mailing statements contain either the same kind of information, or information having the same degree of commercial sensitivity. There is simply too much variety in the types of postal customers who mail in bulk, the types of material mailed, and the types of information contained in mailing statements for there to be a legitimate presumption that all such statements are either exempt or not exempt from mandatory disclosure. A categorical approach does not take sufficiently into account the variety of bulk mailers who file mailing statements in substantially the same format. We find it more appropriate to determine the disclosability of mailing statements on a case-by-case basis, giving each submitter the opportunity to state its views when a request is made.

In addition, while we think that it is reasonable to expect the submitter to inform the Postal Service affirmatively that he or she individually wishes to have the opportunity to object to disclosure, we do agree with the comment that it should not be necessary to provide the same notice repetitiously on information that is substantially the same. Accordingly, we are modifying the designation procedures in § 265.8(e) by adding a new paragraph (3) to provide a simplified process for recurrent submissions.

Finally, one commenter objected to the provision in proposed § 265.8(b)(1) for notification by posting or publishing to numerous submitter of the same type of information, when the Postal Service considers their numbers too great for individual notification. The commenter is concerned that submitters would not actually learn of a request if posting or publishing is used.

The commenter suggested that actual notice imposes a relatively slight burden on the Postal Service in view of the requirement that the submitter designate a contact person for these purposes. We are inclined to agree; moreover, our experience has suggested little need for this kind of notification. We have deleted the provision from the final rule.

#### List of Subjects in 39 CFR Part 265

Release of Information, Postal Service.

For the reasons set out in this document, part 265 of title 39, CFR, is amended as follows:

#### PART 265—RELEASE OF INFORMATION

1. The authority citation for part 265 continues to read as follows:

Authority: 39 U.S.C. 401; 5 U.S.C. 552.

2. Sections 265.8 through 265.10 are redesignated as §§ 265.9 through 265.11, and a new § 265.8 is added to read as follows:

##### § 265.8 Business information; procedures for predisclosure notification to submitters.

(a) In general. This section provides a procedure by which persons submitting business information to the Postal Service can request that the information not be disclosed pursuant to a request under the Freedom of Information Act. This section does not affect the Postal Service's right, authority, or obligation to disclose information in any other context, nor is it intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the Postal Service, its officers, or any person. Existing rights of submitters are also unaffected. For purposes of this section, the following definitions apply:

(1) *Business information* means commercial or financial information provided directly or indirectly to the Postal Service by a submitter that arguably is protected from disclosure under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4), which is restated in § 265.6(b)(2).

(2) *Submitter* means any person or entity who provides business information, directly or indirectly, to the Postal Service. The term includes, but is not limited to, corporations, state governments, and foreign governments.

(b) Notice to submitters. (1) The custodian shall, to the extent permitted by law, provide a submitter with prompt written notice of a Freedom of Information Act request for the submitter's business information whenever required under paragraph (c) of this section, except as provided in paragraph (d) of this section, in order to afford the submitter an opportunity to object to disclosure pursuant to paragraph (f) of this section. Such written notice shall either describe the exact nature of the business information requested or provide copies of the records or portions of records containing the business information. In the case of an administrative appeal, the General Counsel shall be responsible for providing such notification as may be appropriate under this section.

(2) When notice is given to a submitter under paragraph (b)(1) of this section, the requester also shall be

notified that notice and an opportunity to object are being provided to the submitter pursuant to this section.

(c) When notice is required. Notice shall be given to a submitter whenever:

(1) The submitter has in good faith designated the information as information deemed protected from disclosure under Exemption 4, in accordance with the procedure described in paragraph (e) of this section; or

(2) In the opinion of the custodian, or of the General Counsel in the case of an administrative appeal, it is likely that disclosure of the information would result in competitive harm to the submitter.

(d) Exceptions to notice requirements. The notice requirements of paragraph (b) of this section shall not apply if:

(1) The Postal Service determines without reference to the submitter that the information will not be disclosed;

(2) The information lawfully has been published or has been officially made available to the public;

(3) Disclosure of the information is required by law (other than the Freedom of Information Act, 5 U.S.C. 552); or

(4) Disclosure of the particular kind of information is required by a Postal Service regulation, except that, in such case, advance written notice of a decision to disclose shall be provided to the submitter if the submitter had provided written justification for protection of the information under Exemption 4 at the time of submission or a reasonable time thereafter.

(e) Procedure for designating business information at the time of its submission. (1) Submitters of business information shall use good-faith efforts to designate, by appropriate markings, either at the time of submission or at a reasonable time thereafter, those portions of their submissions which they deem to be protected from disclosure under Exemption 4. Each record, or portion thereof, to be so designated, shall be clearly marked with a suitable legend such as Privileged Business Information—Do Not Release. When the designated records contain some information for which an exemption is not claimed, the submitter shall clearly indicate the portions for which protection is sought.

(2) At the time a designation is made pursuant to paragraph (e)(1) of this section, the submitter shall furnish the Postal Service with the name, title, address and telephone number of the person or persons to be contacted for the purpose of the notification described in paragraph (b) of this section.



(3) Submitters who provide to a postal facility business information on a recurring basis and in substantially identical form may use the following simplified process: The first submission will provide in full the information required in paragraphs (e)(1) and (2) of this section; shall identify the type of information, e.g., PS Form 3602, to which it is intended to apply; and shall state that it is intended to serve as a designation for all of the information of this type that is submitted to the particular facility. Thereafter when providing this type of information, the submitter need only mark a submission with a reference to the designation, e.g., Privileged: see letter of 4-1-91. By written agreement with the head of the facility, even this marking may be dispensed with if it is not necessary to alert postal employees at that facility of the claim of exemption.

(4) A designation made pursuant to paragraph (e) of this section shall be deemed to have expired ten years after the date the records were submitted unless the submitter requests, and provides reasonable justification for, a designation period of greater duration.

(5) The Postal Service will not determine the validity of any request for confidential treatment until a request for disclosure of the information is received.

(f) Opportunity to object to disclosure. Through the notice described in paragraph (b) of this section, the submitter shall be afforded a reasonable period of time within which to provide the Postal Service with a detailed written statement of any objection to disclosure. Such statement shall specify all grounds for withholding any of the information under any exemption of the Freedom of Information Act and, in the case of Exemption 4, shall demonstrate why the information is contended to be a trade secret or commercial or financial information that is privileged or confidential. Whenever possible, the submitter's claim of confidentiality should be supported by a statement or certification by an officer or authorized representative of the submitter that the information in question is in fact confidential, has not been disclosed to the public by the submitter, and is not routinely available to the public from other sources. Information provided by a submitter pursuant to this paragraph may itself be subject to disclosure under the FOIA.

(g) Determination that confidential treatment is warranted. If the custodian determines that confidential treatment is warranted for any part of the requested records, he shall inform the requester in writing in accordance with the procedures set out in § 265.7(d) of this

chapter, and shall advise the requester of the right to appeal. A copy of the letter of denial shall also be provided to the submitter of the records in any case in which the submitter had been notified of the request pursuant to paragraph (c) of this section.

(h) Notice of intent to disclose. The custodian, in the case of an initial request, or the General Counsel, in the case of an appeal, shall consider carefully a submitter's objections and specific grounds for nondisclosure prior to determining whether to disclose business information. In the event of a decision to disclose business information over the objection of the submitter, the submitter shall be furnished a written notice which shall include:

(1) A description of the business information to be disclosed;

(2) A statement of the reasons for which the submitter's disclosure objections were not sustained; and

(3) The specific date upon which disclosure will occur. Such notice of intent to disclose shall be forwarded to the submitter a reasonable number of days prior to the specified disclosure date and the requester shall be notified likewise.

(i) Notice of FOIA lawsuit. Whenever a requester brings suit seeking to compel disclosure of business information, the General Counsel shall promptly notify the submitter.

Stanley F. Mires,

Assistant General Counsel, Legislative Division.

[FR Doc. 91-26734 Filed 11-6-91; 8:45am]

BILLING CODE 7710-12-M

## GENERAL SERVICES ADMINISTRATION

### 41 CFR Part 101-47

[FPMR Amendment H-182]

#### Utilization and Disposal of Real Property

**AGENCY:** Federal Property Resources Service, General Services Administration.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the Federal Property Management Regulations by revising the delegations of authority granted to the Department of Defense, the Department of the Interior, and the Department of Agriculture for the utilization and disposal of real property and related personal property having a total estimated fair market value of less than \$1,000. An increase from \$1,000 to \$15,000 in the estimated fair market

value threshold is intended to promote the efficiency of the disposal process, expedite the transfer of property, and reduce the manpower and cost of disposals.

**DATES:** This regulation is effective November 7, 1991.

**FOR FURTHER INFORMATION CONTACT:** Marjorie L. Lomax, Director, Policy and Planning Division, Office of Real Estate Policy and Sales (202-501-0052).

**SUPPLEMENTARY INFORMATION:** The General Services Administration (GSA) has determined that this rule is not a major rule for the purpose of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of \$100 million or more; a major increase in costs to consumers or others; or significant adverse effects. Therefore, a Regulatory Impact Analysis has not been prepared. GSA has based all administrative decisions underlying this rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

#### List of Subjects in 41 CFR Part 101-47

Surplus Government property,  
Government property management.

## PART 101-47—UTILIZATION AND DISPOSAL OF REAL PROPERTY

1. The authority citation for part 101-47 continues to read as follows:

Authority: Sec. 205(c), 63 Stat. 390; (40 U.S.C. 486(c)).

### Subpart 101-47.6—Delegations

2. Section 101-47.601 is amended by revising paragraph (a) to read as follows:

§ 101-47.601 Delegation to Department of Defense.

(a) Authority is delegated to the Secretary of Defense to determine that excess real property and related personal property under the control of the Department of Defense having a total estimated fair market value, including all the component units of the property, of less than \$15,000 as determined by the Department of Defense, is not required for the needs and responsibilities of Federal agencies; and thereafter to dispose of said property by means deemed advantageous to the United States.

\* \* \* \* \*



3. Section 101-4/ 602 is amended by revising paragraph (a) to read as follows:

**§ 101-47.602 Delegation to the Department of Agriculture.**

(a) Authority is delegated to the Secretary of Agriculture to determine that excess real property and related personal property under the control of the Department of Agriculture having a total estimated fair market value, including all the component units of the property, of less than \$15,000 as determined by the Department of Agriculture, is not required for the needs and responsibilities of Federal agencies; and thereafter to dispose of said property by means deemed advantageous to the United States.

4. Section 101-47.603 is amended by revising paragraph (b) to read as follows:

**§ 101-47.603 Delegation to the Department of the Interior.**

(b) Authority is delegated to the Secretary of the Interior to determine that excess real property and related personal property under his control having a total estimated fair market value, including all components of the property, of less than \$15,000 as determined by the Secretary, is not required for the needs and responsibilities of Federal agencies; and thereafter to dispose of the property by means most advantageous to the United States.

5. Section 101-47.604 is amended by revising the heading and paragraphs (a) and (g) to read as follows:

**§ 101-47.604 Delegation to the Department of the Interior, the Department of Health and Human Services, and the Department of Education.**

(a) The Secretary of the Interior, the Secretary of Health and Human Services, and the Secretary of Education, are delegated authority to transfer and to retransfer to each other, upon request, any of the property of either agency which is being used and will continue to be used in the administration of any functions relating to the Indians. The term "property," as used in this § 101-47.604, includes real property and such personal property as the Secretary making the transfer or retransfer determines to be related personal property.

(g) The Secretary of the Interior, the Secretary of Health and Human Services, and the Secretary of

Education, are authorized to redelegate any of the authority contained in this § 101-47.604 to any officers or employees of their respective departments.

Dated: September 27, 1991.

**Richard G. Austin,**

*Administrator of General Services.*

[FR Doc. 91-26814 Filed 11-6-91; 8:45 am]

BILLING CODE 6820-96-M

**DEPARTMENT OF THE INTERIOR**

**Bureau of Land Management**

**43 CFR Public Land Order 6903**

[ID-943-4214-10; IDI-15701A]

**Partial Revocation of Secretarial Order Dated September 29, 1922; Idaho**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Public Land Order.

**SUMMARY:** This order revokes a Secretarial order insofar as it affects 7.74 acres of National Forest System lands withdrawn for the Bureau of Land Management's Powersite Classification No. 50 in the Nez Perce National Forest. The lands are within a wilderness area which precludes power development. This action will open the lands to such forms of disposition as may by law be made of National Forest System lands. The lands will remain closed to mining and mineral leasing by an overlapping wilderness area withdrawal.

**EFFECTIVE DATE:** December 9, 1991.

**FOR FURTHER INFORMATION CONTACT:**

Larry R. Lievsay, BLM Idaho State Office, 3380 Americana Terrace, Boise, Idaho 83706, 208-384-3166.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. The Secretarial Order dated September 29, 1922, which established Powersite Classification No. 50, is hereby revoked insofar as it affects the following described lands:

**Boise Meridian**

T. 26 N., R. 10 E.,

Secs. 21 and 28, tracts 37 and 38.

The areas described aggregate 7.74 acres in Idaho County.

2. The lands will remain closed to the mining and mineral leasing laws by the provisions of the Frank Church River of No Return Wilderness Area.

3. At 9 a.m. on December 9, 1991, the lands described in paragraph 1 above shall be opened to such forms of

disposition as may by law be made of National Forest System lands, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law.

Dated: October 25, 1991.

**Dave O'Neal,**

*Assistant Secretary of the Interior.*

[FR Doc. 91-26893 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-66-M

**43 CFR Public Land Order 6904**

[CO-930-4214-10; COC-0126472]

**Withdrawal of National Forest System Land for Protection of a Forest Service Observation Site; Colorado**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Public Land Order.

**SUMMARY:** This order withdraws 20 acres of National Forest System land from mining for 20 years to protect facilities at an observation point. The land remains open to such forms of disposition as may by law be made of National Forest System land and to mineral leasing.

**EFFECTIVE DATE:** November 7, 1991.

**FOR FURTHER INFORMATION CONTACT:**

Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215-7076, 303-239-3706.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Subject to valid existing rights, the following described National Forest System land is hereby withdrawn from location and entry under the United States mining laws (30 U.S.C. ch. 2 (1988)), but not from leasing under the mineral leasing laws, to protect existing facilities at the North Clear Creek Falls Observation Site:

**New Mexico Principal Meridian**

**Rio Grande National Forest**

T. 42 N., R. 3 W.,

Sec. 36, E $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ .

The area described contains 20 acres of land in Hinsdale County.

2. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of the land under lease, license, or permit, or governing the disposal of the mineral or vegetative resources other than under the mining laws.



3. The withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1988), the Secretary determines that the withdrawal shall be extended.

Dated: October 25, 1991.

Dave O'Neal,

Assistant Secretary of the Interior.

[FR Doc. 91-26892 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-JB-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Chapter I

[GEN Docket No. 90-314; FCC 91-338]

### New Personal Communications Services

**AGENCY:** Federal Communications Commission.

**ACTION:** Policy Statement and Order.

**SUMMARY:** This Policy Statement addresses frequency allocations and other policy issues related to new personal communications services (PCS), orders that an *En Banc* hearing on PCS issues be scheduled, and announces that the Commission will empanel a PCS technical advisory committee. This action provides preliminary guidance for the development of PCS. The intended effect is to further regulatory consideration of PCS issues that will facilitate industry development of PCS.

**EFFECTIVE DATE:** December 9, 1991.

**FOR FURTHER INFORMATION CONTACT:** Tom Mooring, Spectrum Engineering Division, Office of Engineering and Technology, (202) 653-8114.

**SUPPLEMENTARY INFORMATION:** Adopted October 24, 1991; released October 25, 1991.

### Text of the Policy Statement and Order

The Commission issues this Policy Statement to provide preliminary guidance for the development of personal communications services (PCS) in the United States and to solicit additional views addressing a wide range of issues affecting future development of PCS. This Policy Statement will serve as the basis for an *En Banc* hearing that we believe will better inform the Commission about this important communications development.

The concept of PCS has grown in scope and complexity since the ideas of second generation cordless telephone service (C<sup>2</sup>-2) and personal

communications networks (PCNs) were introduced about two years ago. A class of mobile and/or portable technologies and services is developing under the name of PCS that promises both advanced generations of current mobile/portable services and new services. Comments filed in response to the Notice of Inquiry in this proceeding indicate broad interest from new entities such as cable TV providers, microwave common carriers, and private radio entities, in addition to the local exchange carriers and cellular radio telephone providers.<sup>1</sup> Equipment manufacturers also have shown strong interest in unregulated, wireless office concepts. Computer manufacturers who envision PCS providing networking capabilities for future personal computers also have entered the field. While it seems certain that these new underlying technologies will offer an array of advanced voice and data services, such as improved wireless links for computers and medical equipment, PCS will provide the more fundamental capability of communicating directly to individuals rather than locations.

The Commission intends to broadly define personal communications services and make available an adequate amount of spectrum to foster the development of innovative and competitive markets for these services.<sup>2</sup> The spectrum allocation should facilitate local, regional, national and international uses. Additionally, the spectrum should be allocated in phases in order not to find early developments precluding later ones. The first phase should occur in 1992.

Important equipment, cost and international considerations suggest that a portion of the spectrum to be allocated should come from 1.8 to 2.2 GHz. We recognize that serious issues may exist for the incumbents in this band and we intend to reallocate the spectrum needed for PCS with minimum disruption to existing users. Explorations of spectrum availability in that band should proceed to a successful conclusion and should answer the questions dealing with sharing and the cost of substituting services. We also observe that in preparing for the 1992 World Administrative Radio Conference (WARC), the Commission proposed to maintain the primary mobile service allocations in the 1.8 to 2.2 GHz band.

<sup>1</sup> See Notice of Inquiry in GEN Docket No. 90-314, 5 FCC Rcd 3995 (1990).

<sup>2</sup> Consistent with this broad definition, we will consider the data PCS proposed by Apple Computer, Inc. (RM-7618) as part of the family of PCS services to be addressed in this proceeding.

This would provide the United States with the flexibility to implement PCS based on domestic needs. We intend to consider the results of the WARC in developing our domestic PCS allocations.

Additionally, PCS developments will be encouraged in less congested bands. We will monitor closely current experiments in those bands and license quickly future experiments aimed at utilizing unused frequencies for this family of services.

We will encourage significant flexibility in the development of technologies and services. Anticipating, however, difficult issues dealing with transmission systems, interference avoidance, inter and intra industry protocols, roaming and other technical issues, we will empanel an advisory committee to help resolve those issues. If necessary, the advisory committee will make recommendations to the Commission for establishing rules when issues cannot be privately resolved.

Mobile services traditionally have been provided pursuant to both common carrier and private regulatory schemes. Each has its advantages and disadvantages. We lack sufficient information now to determine whether common carriage, private carriage, or some combination of both concepts will be optimal for PCS. The regulatory scheme we eventually decide upon will depend in part upon public interest factors such as our desire to promote the rapid development of this service and our interest in promoting competition in PCS and in telecommunications generally.<sup>3</sup>

Commission policy towards PCS will be guided by these general conclusions. But we do not have sufficient information before us to propose tentative conclusions on how all the issues should be resolved. We seek additional information on issues such as how licenses should be assigned and policies affecting participation in PCS by new entrants, e.g., parties not currently engaged in the provision of telecommunications services, including the application of pioneer's preference and possible financial qualifications issues. The *En Banc* hearing will be

<sup>3</sup> The Commission is in the process of forming a Small Business Advisory Committee. One of the functions of the Small Business Advisory Committee will be to review FCC dockets in new, emerging technologies/services and to assess the policy implications of such developments on small businesses, including the impact on rural businesses and minority and female entrepreneurs. Included in this Committee's work will be an assessment of the potential impact of PCS allocation and licensing decisions on the participation of small businesses and new entrants.



structured to address these and other questions relating to four general areas:

(1) *Definition of personal communications services*, for example, the types of service anticipated and demand for each service type;

(2) *Spectrum requirements*, such as the amount of spectrum required for PCS, the timing of spectrum allocation, the desirable spectrum for various members of the PCS family of services, bandwidth requirements, the accommodation of current licensees, and the ability to share spectrum;

(3) *Technologies for personal communications services*, such as the relative advantages of competing technologies for different applications, the degree of technical flexibility that should be granted PCS licensees, the results of PCS experiments or trials, the role of unregulated low power devices, and the need for mandated Commission standards; and

(4) *Regulatory issues*, such as the method of assigning licenses, the appropriate geographic scope of licenses, the feasibility of a voluntary negotiated approach to relocating existing users, the merits of exclusive as compared to non-exclusive assignments, privacy implications of personal radio-based communications services, the terms and conditions of interconnection to the public switched network, the need for a new numbering plan, the need to accommodate roaming subscribers, licensee eligibility, regulatory jurisdiction, and appropriate regulatory treatment of PCS.

#### Ordering Clause

Accordingly, it is ordered that, the Commission shall hold, on December 5, 1991, an *En Banc* hearing.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 91-26955 Filed 11-6-91; 8:45 am]

BILLING CODE 6712-01-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[MM Docket No. 87-121]

#### FM Broadcast Services; Short-spaced Station Assignments With Reduced Facilities and/or Directional Antenna Systems

AGENCY: Federal Communications Commission.

ACTION: Final rule; notice of effective date.

**SUMMARY:** This is a notice of the retroactive effective date of new rules adopted by the Commission in the Report and Order (Report) of this proceeding (54 FR 9800, March 8, 1989). That Report adopted provisions to allow routine short-spaced FM broadcast station assignments. Pending approval of the Office of Management and Budget (OMB) for new information collection requirements, the Report stated that the Commission would issue a Public Notice, to be published in the *Federal Register*, announcing the effective date of the rules. Subsequent to receiving OMB's approval, the Commission issued a Public Notice on June 26, 1989, Mimeo No. 3384, announcing that the adopted rules were effective as of the date of that Public Notice. Inadvertently, however, the Public Notice was not published in the *Federal Register*. Therefore, the publication of this summary announces the effective date retroactively.

**EFFECTIVE DATE:** June 26, 1989 (retroactive).

**FOR FURTHER INFORMATION CONTACT:** Bernard Gorden, Mass Media Bureau, Policy and Rules Division, (202) 632-9660.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Public Notice of June 26, 1989, Mimeo No. 3384. The complete text of this Public Notice is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC., and also may be purchased from the Commission's copy contractor, Downtown Copy Center, at (202) 452-1422, 1919 M Street, NW., room 246, Washington, DC 20554.

#### Synopsis of Public Notice

1. The Report adopted rule changes which required the collection of additional information in FCC Forms 301 and 340. Implementation of these rule changes was conditioned upon OMB approval of modifications to FCC Forms 301 and 340 reflecting the new information collection requirements. Effective June 26, 1989, OMB approved the necessary changes to FCC Forms 301 and 340. Thus, the rule changes adopted in MM Docket No. 87-121 are effective as of that date.

2. Accordingly, the rule amendments to 47 CFR part 73 are retroactively effective on June 26, 1989. This action is taken pursuant to authority contained in sections 4 and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 154 and 303.

#### List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 91-26795 Filed 11-6-91; 8:45 am]

BILLING CODE 6712-01-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[MM Docket No. 91-176; RM-7738]

#### Radio Broadcasting Services; Fortuna and Rohnerville, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

**SUMMARY:** This document reallocates Channel 263A from Rohnerville to Fortuna, California, and modifies the permit of North Star Communications for Station KQEX(FM) to specify operation on Channel 262C2, as requested, pursuant to the provisions of section 1.420(i) of the Commission's Rules. Rohnerville has been annexed by Fortuna and no longer exists as a separate community. The allotment of Channel 262C2 to Fortuna will provide that community with its first local, wide area coverage FM transmission service. See 56 FR 29615, June 28, 1991. Coordinates used for Channel 262C2 at Fortuna are those for the presently authorized site for Station KQEX(FM) at 40-30-03 and 124-17-10. With this action, the proceeding is terminated.

**EFFECTIVE DATE:** December 23, 1991.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 91-176, adopted October 22, 1991, and released November 4, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, Downtown Copy Center, (202) 452-1422, 1714 21st Street, NW., Washington, DC 20036.

#### List of Subjects in 47 CFR Part 73

Radio broadcasting.



**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 263A, Rohnerville, and adding Channel 262C2, Fortuna.

Federal Communications Commission.

Michael C. Ruger,

*Assistant Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 91-26959 Filed 11-6-91; 8:45 am]

BILLING CODE 6712-01-M

**47 CFR Part 73**

[MM Docket No. 91-211; RM-7548]

**Radio Broadcasting Services; Tallulah, LA**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Sharing, Inc., licensee of Station KBYO-FM, Channel 285A, Tallulah, Louisiana, substitutes Channel 283C3 for Channel 285A at Tallulah, and modifies Station KBYO-FM's license to specify operation on the higher powered channel. See 56 FR 33413, July 22, 1991. Channel 283C3 can be allotted to Tallulah in compliance with the Commission's minimum distance separation requirements and can be used at the transmitter site specified in Station KBYO-FM's license. The coordinates for Channel 283C3 at Tallulah are North Latitude 32-24-10 and West Longitude 91-04-00. With this action, this proceeding is terminated.

**EFFECTIVE DATE:** December 23, 1991.

**FOR FURTHER INFORMATION CONTACT:**

Pamela Blumenthal, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 92-211, adopted October 24, 1991, and released November 4, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1714 21st Street, NW., Washington, DC 20036.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Louisiana, is amended by removing Channel 285A and adding Channel 283C3 at Tallulah.

Federal Communications Commission.

Michael C. Ruger,

*Assistant Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 91-26960 Filed 11-6-91; 8:45 am]

BILLING CODE 6712-01-M

**47 CFR Part 73**

[MM Docket No. 90-587; RM-7479]

**Radio Broadcasting Services; Tusculum, TN**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Tusculum Regional Broadcasting Company, allots Channel 276A to Tusculum, Tennessee. See 55 FR 49923, December 3, 1990. Channel 276A can be allotted to Tusculum, Tennessee, in compliance with the Commission's minimum distance separation requirements with a site restriction of 8.0 kilometers (5.0 miles) east to avoid a short-spacing to Station WIMZ-FM, Channel 278C, Knoxville, Tennessee. The coordinates for the allotment of Channel 276A at Tusculum are North Latitude 36-10-58 and West Longitude 82-40-14. With this action, this proceeding is terminated.

**DATES:** *Effective Date:* December 23, 1991.

The window period for filing applications will open on December 24, 1991, and close on January 23, 1992.

**FOR FURTHER INFORMATION CONTACT:**

Pamela Blumenthal, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 90-587, adopted October 24, 1991, and released November 4, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased

from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1714 21st Street, NW., Washington, DC 20036.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Tennessee, is amended by adding Channel 276A, Tusculum.

Federal Communications Commission.

Michael C. Ruger,

*Assistant Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 91-26961 Filed 11-6-91; 8:45 am]

BILLING CODE 6712-01-M

**47 CFR Part 73**

[MM Docket No. 91-107; RM-7640]

**Radio Broadcasting Services; Huntingdon and Atwood, TN**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Big Tenn Communications Company, Inc., reallocates Channel 229A from Huntingdon to Atwood, Tennessee. See 56 FR 18558, April 23, 1991. Channel 229A can be allotted to Atwood in compliance with the Commission's minimum distance separation requirements with site restriction of 4.8 kilometers (3.0 miles) south to accommodate Big Tenn's desired transmitter site. The coordinates for the allotment of Channel 229A to Atwood, Tennessee, are North Latitude 35-56-00 and West Longitude 88-40-00. With this action, this proceeding is terminated.

**EFFECTIVE DATE:** December 23, 1991.

**FOR FURTHER INFORMATION CONTACT:**

Pamela Blumenthal, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 91-107, adopted October 24, 1991, and released November 4, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of



this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1714 21st Street, NW., Washington, DC 20036.

#### List of Subjects in 47 CFR Part 73

Radio broadcasting.

#### PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

#### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Tennessee, is amended by removing Channel 229A at Huntingdon and adding Channel 229A, Atwood.

Federal Communications Commission.

Michael C. Ruger,

Assistant Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 91-26958 Filed 11-6-91; 8:45 am]

BILLING CODE 6712-01-M

#### DEPARTMENT OF TRANSPORTATION

##### National Highway Traffic Safety Administration

#### 49 CFR Part 571

[Docket No. 81-2; Notice 12]

RIN 2127-AE16

##### Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices, and Associated Equipment

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), DOT.

**ACTION:** Mooting of petition for reconsideration; final rule.

**SUMMARY:** This notice moots a petition by Ford Motor Company for reconsideration of the effective dates of the final rule first permitting, then requiring center high-mounted stop lamps (CHMSLs) on vehicles other than passenger cars (light trucks). Ford had requested that the effective dates for both permissive and mandatory installation of CHMSLs be delayed until the effective date for the amendment permitting the combination of light truck CHMSLs with cargo lamps, if that date were later. The petition is mooted because the agency, in this notice, is amending Federal Motor Vehicle Safety Standard No. 108, as proposed, to allow the physical combination (but not the optical combination) of cargo lamps with light truck CHMSLs with an effective date that coincides with the

effective date for permissive installation of light truck CHMSLs.

**DATES:** The effective date of the final rule is December 9, 1991.

**FOR FURTHER INFORMATION CONTACT:** Richard Van Iderstine, Office of Rulemaking, NHTSA (202-366-5280).

**SUPPLEMENTARY INFORMATION:** On April 19, 1991, NHTSA published a final rule requiring the installation of center high-mounted stop lamps (CHMSLs) on multipurpose passenger vehicles, trucks, and buses with an overall width of less than 80 inches, and whose GAWR is 10,000 pounds or less (referred to, for convenience, as "light truck CHMSLs") (56 FR 16015). The final rule requires mandatory installation of light truck CHMSLs on vehicles manufactured on and after September 1, 1993, with optional installation of conforming lamps permitted as of September 1, 1992. Simultaneously, NHTSA published a supplemental notice of proposed rulemaking to allow cargo-bed lamps to be physically combined, but not optically combined, with light truck CHMSLs (56 FR 16052). The proposed effective date of this amendment was September 1, 1992.

#### Petition for Reconsideration

Ford Motor Company filed the only petition for reconsideration of the light truck CHMSL final rule. It requested that the optional and mandatory effective dates (September 1, 1992, and September 1, 1993, respectively) be stated in alternative terms, namely September 1, 1992 or 1993, or the actual effective date of the rule permitting the combination of light truck CHMSLs and cargo-bed lamps.

The reason for Ford's request is its intention to offer the combination lamps in several of its products lines, beginning with the 1992 model year. It was concerned that the proposed effective date of September 1, 1992 might be delayed. However, this notice responds to Ford's concern by adopting an effective date that is 30 days after publication of the notice in the Federal Register, thereby mooted the petition for reconsideration.

#### Combining the Light Truck CHMSL With a Cargo Lamp

The supplemental NPRM was issued in response to requests by Chrysler, Ford, and General Motors that the CHMSL be permitted to be combined with the cargo-bed lamp typically found on the rear of the cab of pickup trucks. They reasoned that despite the specific prohibition in S5.4 against the combining of a CHMSL with any other lamp, the combination of a CHMSL with a cargo-

bed lamp would have absolutely no negative safety effect because of the nature and use of the two lamps. The cargo-bed lamp is a white colored lamp actuated by the user for illuminating the cargo area of the truck body bed. It is typically electrically connected to the interior dome lamp. Thus, the likelihood of driving with the cargo-bed lamp illuminated is low. Commenters also said that the two lamps would not likely be optically combined, since they are two different colors, but they could be in a common housing, possibly with a cargo lamp flanking each side of the CHMSL for symmetrical appearance. General Motors specifically suggested a prohibition of optical combination, however.

The agency saw no reason to prohibit the physical combination of a CHMSL and a cargo lamp. However, it was concerned about the possible effect on safety of an optical combination, and did not propose to allow it.

Although the rule permits the use of a physically combined CHMSL and cargo lamp, manufacturers must ensure that the combined lamp does not operate in such a way as to impair the effectiveness of the CHMSL, a lamp required by Standard No. 108.

#### Comments on the Supplemental Proposal

Ford, General Motors (GM), Chrysler Corporation, and Truck-Lite filed comments on the supplemental proposal, and were unanimous in their support of it. The questions and concerns raised were minor, and are discussed below.

#### A. Definition of Cargo-Bed Lamp

NHTSA proposed that a cargo-bed lamp be defined as "a lamp that is mounted on the rear of the cab of a truck or multipurpose passenger vehicle with an open cargo bed and that is used to illuminate the cargo bed."

Ford commented that the proposed definition limited the application of the lamp to vehicles that have open cargo beds. It noted that the lamps can also serve as a utility lamp on closed vehicles such as vans and utility trucks to illuminate the area to the rear of the vehicle where cargo would be loaded and unloaded. Ford suggested that the lamp be called simply a "cargo lamp", and defined as a supplemental lamp that provides "illumination to the rear of the vehicle or the vehicle cab to unload cargo or equipment in an environment of insufficient light."

NHTSA concurs in principle with this comment. It has no wish to restrict the definition so as to exclude lamps that



aid in unloading cargo from vehicles other than those with open beds. Accordingly, NHTSA has decided to rename the lamp a "cargo lamp", and to define it as a "lamp that is mounted on the exterior of a multipurpose passenger vehicle, truck, or bus for the purpose of providing illumination to load and unload cargo."

#### *B. Permitting Optically Combined Cargo Lamps and Light Truck CHMSLs*

In its comments, Ford requested that NHTSA consider allowing optically combined cargo lamps and light truck CHMSLs in future rulemaking stating that this would offer efficiencies in cost, manufacturing, and design. The agency is agreeable to considering this issue in a future rulemaking, and invites interested persons to provide information and views on the performance of such lamp combinations.

#### *C. Whether a Separate Lens Must Be Used for Each Lamp Function*

GM commented that the definition NHTSA proposed for "optically combined" could be interpreted as requiring separate lenses for cargo lamp and CHMSL functions. It anticipates that a combination lamp would have a dual molded, two-color, one-piece lens. Because NHTSA's proposed definition included the words "where the optically functional lens area of the lamp is wholly or partially common to two or more lamp functions" (emphasis supplied), GM fears that, in the case of a one-piece two-color lens, the "optically functional lens area" of such a lens could be interpreted as all inclusive of the optics on both the red and crystal part of the one piece lens, and hence forbidden as an "optical combination."

NHTSA notes that the definition of "optically combined" that was adopted on June 7, 1991 (the definition in SAE J387), pursuant to another rulemaking, contains much the same language as was quoted above. The newly adopted definition includes the phrase "where its optically functional lens area is wholly or partially common to two or more lamp functions." Thus, the recent amendment has not addressed GM's concern.

NHTSA does not consider a combination CHMSL/cargo lamp which uses a dual-molded, two-color, one-piece lens to be "optically combined", provided that the light source(s) for each independent lighting function (CHMSL or cargo) contribute light solely for that function. Such an arrangement results in separate optically functional lens areas for each independent lighting function, and therefore is excluded from the definition of "optically combined" in

SAE J387. Therefore, GM's concern that a two-color lens would not be permitted is unfounded.

#### *D. Allowance of CHMSLs Prior to Optional Compliance Date*

The remark appeared under "Proposed effective date" in the supplemental proposal that "CHMSLs may not be installed on light trucks before" the optional effective date of September 1, 1992. Truck-Lite commented that it was its understanding that such lamps could be installed before the optional effective date as long as they did not impair the effectiveness of the lighting equipment required by Standard No. 108. Ford filed a similar comment. Both cited relevant agency interpretations.

Both Truck-Lite and Ford are correct. A CHMSL may be installed on a vehicle manufactured before September 1, 1992, even if it does not meet light truck CHMSL requirements, as long as it does not impair the effectiveness of the required lighting equipment (§5.1.3 of Standard No. 108, allowing supplemental lamps, subject to the prohibition against impairment). If a manufacturer of trucks or multipurpose passenger vehicles chooses to install a light truck CHMSL on a vehicle manufactured between September 1, 1992, and September 1, 1993 (or, as required, installs it on a vehicle manufactured on and after September 1, 1993), he must comply with all the requirements for light truck CHMSLs.

#### **Effective Date**

The effective date of the amendment allowing the combining of a CHMSL with a cargo bed lamp is 30 days after publication of this notice in the **Federal Register**. The agency wishes to encourage introduction of light truck CHMSLs at the earliest practicable time. There are indications that manufacturers want to combine cargo lamps with CHMSLs, and an early effective date for the amendment adopted by this notice will allow them to do so. Accordingly, it is hereby found for good cause shown that an effective date earlier than one year after issuance of the final rule is in the public interest.

#### **Rulemaking Analyses**

##### *Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures*

NHTSA has considered the impacts of this rulemaking action and has determined that it is not major within the meaning of Executive Order 12291 "Federal Regulation," or significant under Department of Transportation

regulatory policies and procedures. The rule is permissive in nature. NHTSA does not know the extent to which manufacturers will take advantage of the amendment. Manufacturers which do so may realize cost savings of no more than several dollars per vehicle. Thus, the effects of the amendments are so minimal that preparation of a full regulatory evaluation is not necessary.

#### *Regulatory Flexibility Act*

The agency has also considered the effects of this rule in relation to the Regulatory Flexibility Act. I certify that this rule will not have a significant economic effect upon a substantial number of small entities. Lamp manufacturers and manufacturers of vehicles with cargo lamps are generally not small business within the meaning of the Regulatory Flexibility Act. Further, small organizations and governmental jurisdictions will not be significantly affected as the price of new vehicles, if equipped with a combination lamp, should not be more than minimally impacted. Accordingly, no Regulatory Flexibility Analysis has been prepared.

#### *National Environmental Policy Act*

NHTSA has analyzed this rule for purposes of the National Environmental Policy Act. The rule will not have a significant effect upon the environment, as there should be a slight decrease in materials required by the manufacture of a combination lamp rather than two separate lamps, if a manufacturer wishes to avail itself of the option of combining a cargo lamp with a center highmounted stop lamp.

#### *Executive Order 12612 (Federalism)*

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 "Federalism." It has been determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### **List of Subjects in 49 CFR Part 571**

Imports, Motor vehicle safety, Motor vehicles.

In consideration of the foregoing, 49 CFR part 571 is amended as follows:

#### **PART 571—[AMENDED]**

1. The authority citation for part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

2. In § 571.108, S4 *Definitions*, of Standard No. 108, a definition of "cargo



lamp" is added in alphabetical order, and S5.4 is revised, to read:

**§ 571.108 Standard No. 108; Lamps, reflective devices, and associated equipment.**

**S4. Definitions.**

*Cargo lamp* is a lamp that is mounted on a multipurpose passenger vehicle, truck, or bus for the purpose of providing illumination to load or unload cargo.

**S5.4 Equipment combinations.** Two or more lamps, reflective devices, or items of associated equipment may be combined if the requirements for each lamp, reflective device, and item of associated equipment are met, with the following exceptions:

(a) No high-mounted stop lamp shall be combined with any other lamp or reflective device, other than with a cargo lamp.

(b) No high-mounted stop lamp shall be combined optically, as defined by SAE Information Report J387 *Terminology—Motor Vehicle Lighting* NOV 87, with any cargo lamp.

(c) No clearance lamp shall be combined optically, as defined by SAE Information Report J387 *Terminology—Motor Vehicle Lighting* NOV 87, with any taillamp.

Issued on: November 1, 1991.

Jerry Ralph Curry,  
Administrator.

[FR Doc. 91-26855 Filed 11-6-91; 8:45 am]

BILLING CODE 4910-59-M

## DEPARTMENT OF THE INTERIOR

### U.S. Fish and Wildlife Service

#### 50 CFR Part 16

RIN 1018-AB58

#### Importation or Shipment of Injurious Wildlife: Zebra Mussel

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** The U.S. Fish and Wildlife Service (Service) amends 50 CFR 16.13 by adding the zebra mussel (*Dreissena polymorpha*), a small bivalve mollusk native to Europe, to the list of injurious fish, mollusks, and crustaceans. By this action, the Service prohibits importation into, acquisition, or transportation of live zebra mussels, veligers or viable eggs thereof between the continental United States, the District of Columbia,

Hawaii, the Commonwealth of Puerto Rico, or any territory or possession of the United States.

**EFFECTIVE DATE:** December 9, 1991.

**ADDRESSES:** Chief, Division of Fish and Wildlife Management Assistance, U.S. Fish and Wildlife Service, Mail Stop 820-ARLSQ, 1849 C Street, NW., Washington, DC 20240.

**FOR FURTHER INFORMATION CONTACT:** Dr. James G. Geiger, Chief, Division of Fish and Wildlife Management Assistance, telephone (703) 358-1718.

**SUPPLEMENTARY INFORMATION:** The Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (Pub. L. 101-646, 104 Stat. 4761) was passed by Congress on October 27, 1990, and signed by President Bush. Section 1203 of that law contains a provision that amends the Lacey Act (18 U.S.C. 42) by adding the zebra mussel (*Dreissena polymorpha*) to the list of injurious animals contained therein. This requires addition of the zebra mussel to implementing regulations in 50 CFR 16.13.

#### Description of the Final Rule

The regulations contained in 50 CFR part 16 implement the Lacey Act (18 U.S.C. 42) as amended. Under the terms of that law, the importation of certain named wildlife is prohibited, with exceptions. Additionally, the Secretary of the Interior is authorized to prescribe by regulations other nonindigenous wild animals, or viable eggs thereof, which are deemed to be injurious or potentially injurious to the health and welfare of human beings, to the interests of agriculture, forestry, and horticulture, or the welfare and survival of wildlife or wildlife resources of the United States. The Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 added the zebra mussel to the statutory list. The Service accordingly amends 50 CFR 16.13 to reflect the present list of prohibited wildlife. By adding the zebra mussel (*Dreissena polymorpha*) to the list of injurious fish, mollusks, and crustaceans in 18 U.S.C. 42 and now in 50 CFR 16.13, their acquisition, importation into, or transportation between the continental United States, the District of Columbia, Hawaii, the Commonwealth of Puerto Rico, or any territory or possession of the United States by any means whatsoever is prohibited except by permit for zoological, educational, medical, or scientific purposes, or by Federal agencies without a permit solely for their own use upon filing a written declaration with the District Director of Customs at the port of entry. In addition, no live zebra mussel, viable eggs, or

progeny thereof acquired under permit may be sold, donated, traded, loaned, or transferred to any other person unless such person has a permit issued by the Director of the Service. The interstate transportation of any live zebra mussels, veligers or viable eggs thereof that currently may be held in the United States for any purpose not otherwise permitted, would be prohibited.

#### Required Determinations

This rulemaking amends the list of prohibited species in 50 CFR 16.13 to accurately reflect the addition made by section 1203 of Pub. L. 101-646, the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, which amends the U.S. Code (18 U.S.C. 42) by adding the zebra mussel to its list of injurious animals. In order to update the Code of Federal Regulations to conform with Public Law 101-646, it is necessary to add this species to the implementing regulations (50 CFR 16.13). The Service accordingly finds that notice and public procedure are impracticable, unnecessary, and contrary to the public interest. This rulemaking involves no discretionary or policy decisionmaking on the part of the Service, but merely amends its regulation to reflect a change in statute. As such, neither a Determination of Effects nor an Environmental Assessment were required or prepared in conjunction with this rulemaking.

#### Information Collection Requirements

This final rule contains no information collection requirements for which Office of Management and Budget approval is required under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects in 50 CFR Part 16

Fish, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Accordingly, 50 CFR part 16 is amended as described below:

#### PART 16—INJURIOUS WILDLIFE

1. The authority citation for part 16 is revised to read as follows:

Authority: 18 U.S.C. 42 and 19 U.S.C. 42(a)(1).

2. Section 16.13(a)(1) is revised to read as follows:

**§ 16.13 Importation of live or dead fish, mollusks, and crustaceans, or their progeny or eggs.**

(a)(1) The importation, transportation, or acquisition is prohibited of any:

(i) Live fish or viable eggs of the family Clariidae;



(ii) Live crustaceans or viable eggs of mitten crabs, genus *Eriocheir*, and  
 (iii) Live mollusks, veligers or viable eggs of zebra mussels, genus *Dreissena*:  
*Provided*, That the Director may issue permits authorizing the importation, transportation, and possession of such live fish, crustaceans, mollusks or viable eggs or progeny thereof under the terms and conditions set forth in § 16.22.

Dated: March 9, 1991.

Richard N. Smith,  
 Deputy Director.

[FR Doc. 91-26733 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-55-M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 672

[Docket No. 9001184-1042]

#### Groundfish of the Gulf of Alaska

**AGENCY:** National Marine Fisheries Service (NMFS), NOAA, Commerce.

**ACTION:** Establishment of directed fishing allowances; notices of closure to

directed fishing; change or reporting and recordkeeping requirements; correction.

**SUMMARY:** This action corrects a notice that established directed fishing allowances and closed directed fisheries for pollock in the Western and Central pollock subareas of the Gulf of Alaska and changed reporting and recordkeeping requirements. This correction is necessary to inform the public of an alteration to the closure dates for pollock in the Western Pollock Subarea (WSA) and in the Central Pollock Subarea (CSA).

The original closure predictions were based on processor surveys and telephone contacts with the industry prior to openings on October 21, 1991. Since that time, a significant shift of harvest effort from one subarea to another occurred, causing the need to change these closure dates from 12 noon, Alaska local time (A.l.t.), October 26, 1991, in the WSA, and 4 p.m., A.l.t., October 24, 1991, in the CSA, to 12 noon, A.l.t., October 25, 1991, for both subareas.

**EFFECTIVE DATE:** October 24, 1991.

**FOR FURTHER INFORMATION CONTACT:** Jessica A. Gharett, Fisheries

Management Division, NMFS, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** In rule document 91-95563 beginning on page 55096 in the issue of Thursday, October 24, 1991, make the following corrections:

1. On page 55096, first column, under **EFFECTIVE DATES**, the second sentence should read: "Notice of closure for: (1) the Western Pollock Subarea (WSA), 12 noon, A.l.t., October 25, 1991; and (2) the Central Pollock Subarea (CSA), 12 noon, A.l.t., October 25, 1991, both through the remainder of the fishing year."

2. On page 55096, under **ESTABLISHMENT OF DIRECTED FISHING ALLOWANCES AND CLOSURES TO DIRECTED FISHING**, in the third column, eleventh line, change "October 26, 1991", to read "October 25, 1991", and on the twelfth line, change "October 24, 1991", to read "October 25, 1991."

Dated: November 1, 1991.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 91-26853 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-22-M



# Proposed Rules

Federal Register

Vol. 56, No. 216

Thursday, November 7, 1991

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF ENERGY

### Office of the Secretary

#### 10 CFR Part 600

#### Financial Assistance Rules; Miscellaneous Changes

**AGENCY:** Department of Energy.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Energy (DOE) today proposes a number of revisions to subparts A and B of the Financial Assistance Rules, 10 CFR part 600, some of which reflect desired policy changes, some of which are updates to the Rules, and some of which correct errors in the Rules.

**DATES:** Written comments on the proposed rule must be received by December 9, 1991.

**ADDRESSES:** Comments should be addressed to: James J. Cavanagh, Director, Business and Financial Policy Division (PR-122), Office of Procurement, Assistance and Program Management, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585.

#### FOR FURTHER INFORMATION CONTACT:

Edward F. Sharp, Business and Financial Policy Division, (PR-122), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-8192.  
Linda Johnson, Office of the Assistant General Counsel Procurement and Finance (GC-34), U.S. Department of Energy, Washington, DC 20585, (202) 586-1900.

#### SUPPLEMENTARY INFORMATION:

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- I. Introduction
- II. Proposed Changes to 10 CFR part 600.
- III. Review Under Executive Order 12612.
- IV. Review under Executive Order 12291.
- V. Review under the Regulatory Flexibility Act.
- VI. Review under the Paperwork Reduction Act.
- VII. Review under the National Environmental Policy Act.

## VIII. Public Comments.

### I. Introduction

The DOE is today proposing to amend its Financial Assistance Rules (Rules) to implement desired policy changes, update the Rules and correct errors contained therein. The changes will (1) state the need to comply with DOE regulations regarding the use of human subjects in research; (2) expand the criteria justifying a non-competitive financial assistance award to include a statutory mandate to make an award to a specific recipient; (3) include provisions to comply with Executive Order 12699, Seismic Safety of Federal and Federally assisted or Regulated New Building Construction; (4) revise the criteria for selection of unsolicited applications to state that the determination that a competitive solicitation would be inappropriate must be made in light of other solicitations the DOE may already have issued or be planning to issue; (5) elaborate on the nature of the information needed in the Federal Register notice to explain why an award is being made in response to an unsolicited proposal; (6) change the title of § 600.16; (7) modify the merit review requirements to allow a decision not to merit review a renewal award to be made closer in time to the beginning date of the renewal with appropriate approval; (8) change the words "evaluator" and "evaluation" in § 600.16(i) to "reviewer" and "review" to conform to the terminology used in that section; (9) codify previously published class deviations for the Small Business Innovation Research (SBIR) program and make conforming changes elsewhere in the Rules; (10) eliminate the payment provisions regarding the letter of credit system; (11) clarify the requirement regarding single bid or sole source procurements under research awards; (12) correct the reference in § 600.119(d) from 600.118 to 600.33; (13) change the reference in § 600.120(c) from Attachment F of OMB Circular A-110 to OMB Circular A-133; (14) delete references to the Intergovernmental Cooperation Act of 1968 in §§ 600.113 and 600.421 and the Indian Self-Determination Act in § 600.421; (15) update an address included in § 600.14; and (16) correct typographical errors in §§ 600.103, 600.113, 600.420, 600.424, and 600.436.

Language is being added to § 600.2 to highlight the requirement that research

recipients using human subjects must comply with 10 CFR part 745.

The inclusion of an additional ground for justifying the award of financial assistance on a noncompetitive basis recognizes that at times there is a statutory requirement to award funds to a specific recipient.

The provision concerning the use of seismic design and construction standards whenever Federal grants, loans or contracts are used for all or part of the construction costs is included to comply with Executive Order 12699 of January 5, 1990, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction.

The criteria for selection of an unsolicited application is changed to provide that a determination that a project would be inappropriate for a competitive solicitation is not by itself a sufficient ground to award it. Recent, current, or planned solicitations must also be considered in deciding whether to award an unsolicited proposal.

The requirement to publish in the Federal Register an explanation for making an award in response to an unsolicited proposal is being elaborated to stipulate that the explanation must also address the selection criteria for unsolicited proposals.

The title of § 600.16 is being changed to "Objective Merit Review" because the entire merit review process is the subject of the section, not just the affiliation of reviewers as the present title states.

The provisions regarding the merit review of applications currently provide that a determination not to conduct a merit review of a project at renewal must be made no later than one year prior to the renewal date. The change proposed here would permit a waiver of the one year requirement so long as the project officer's supervisor and the responsible official concur in that determination and a review for technical merit is included as part of the determination. It also clarifies the point that awards which do not go through the merit review process are subject to the requirements established for award of noncompetitive financial assistance.

The words "evaluator" and "evaluation" in § 600.16(i) are being changed to "reviewer" and "review." The former terms have been in the Rules for a number of years and were inadvertently retained when this section



was revised in October, 1988 to add the provisions (which use the terms "reviewer" and "review") concerning objective merit review.

Six class deviations affecting the Rules dealing with the Small Business Innovation Research (SBIR) program were published in the *Federal Register* on May 22, 1990 (55 FR 21008) and are herein codified. These deviations (1) simplify record-keeping requirements for Phase I SBIR recipients; (2) permit, at the discretion of the Contracting Officer, lump sum payments to be made to Phase I recipients; (3) permit Phase II SBIR recipients to have budget periods of up to 24 months; (4) require awarding agency approval for time extensions of project periods; (5) require awarding agency approval of any procurement expected to exceed \$25,000 which is being awarded on a sole source basis or for which only one bid was received; (6) permit a fee or profit to be paid to SBIR recipients. Conforming changes are being made in other sections as well. Questions have arisen about whether the DOE rulemaking dated October 13, 1989 (54 FR 41943), regarding the elimination of many prior approval requirements, was intended to apply to the prior approval provisions in § 600.119 which deal with procurements under research awards. That rulemaking was intended to apply to procurements under research awards, except for SBIR awards, and changes have been made to § 600.119 to clarify that point.

A typographical error is being corrected in § 600.103(f)(1).

A typographical error is being corrected in § 600.113(e).

References to the Intergovernmental Cooperation Act of 1968 (ICA) in §§ 600.113 and 600.421 and the Indian Self-Determination Act in § 600.421 have been deleted. The ICA has been amended by the Cash Management Improvement Act of 1990 (CMIA), which in particular has affected the requirements regarding state interest payments. The specific impact of the CMIA will not be clear, however, until the Treasury Department completes its implementing regulations. In light of the changing nature of the legal requirements in this area, the Department is concerned that any attempt to list and explicate the relevant statutes could create more confusion than it resolves and would necessitate frequent revision of this regulation. Therefore, all references to specific statutes have been eliminated.

As a result of the phase-out of the Treasury Financial Communication System Letter-of-Credit, and the resultant need for the DOE to convert to another payment system, references to

letter-of-credit as a payment mechanism in § 600.112 are being removed. The section on payments is also being restructured to more closely resemble the payment section in subpart E.

As a result of the promulgation of OMB Circular A-133 ("Audits of Institutions of Higher Learning and Other Non-Profit Institutions") on March 16, 1990, the reference in the Financial Assistance Rules to OMB Circular A-110, Attachment F, which deals with the same topic, is being replaced with a reference to Circular A-133.

An address is being changed in § 600.14(c).

A correction of a citation is being made in § 600.119(d)(2).

A typographical error is being corrected in § 600.420(a).

A typographical error is being corrected in § 600.424(b)(7)(ii).

A typographical error is being corrected in § 600.436(g)(2)(i).

## II. Proposed Changes to 10 CFR Part 600

A new paragraph (c) is being added to § 600.2 to note the requirement that research involving human subjects must comply with 10 CFR part 745.

A new paragraph (G) is being added to § 600.7(b)(2)(i) to recognize as a grounds for issuing a financial assistance award on a noncompetitive basis a statutory requirement to issue an award to a particular recipient. To use this justification, the recipient must be specifically designated in the statute. The current paragraph (G) has been redesignated (H).

A new paragraph (c) is being added to § 600.12 to require that appropriate seismic design and construction standards be met if DOE funds are used in any building construction.

Section 600.14(c) is changed to update the address for receipt of a guide for preparing unsolicited applications/proposals.

Section 600.14(e)(1)(ii) is changed to provide that the determination of whether it would be appropriate to initiate a competitive solicitation prior to making an award of an unsolicited proposal is one factor to be considered along with whether an application would be eligible for award under a recent, current, or planned solicitation.

Section 600.14(f) is being revised to require that the explanation for making an award in response to an unsolicited application address the selection criteria in § 600.14(e)(1).

The title to § 600.16 is being changed from "Reviewer affiliations" to "Objective merit review".

Section 600.16(a)(3)(ii) is being revised to permit a waiver to the requirement that a determination not to merit review

a renewal be made at least one year prior to the renewal date. In such a case there must be a written justification, approved by the project officer's supervisor and the responsible official, explaining the reasons that a merit review is not being done. Further, the justification must contain a review of the technical merit of the project. The section is also being revised to clarify the point that if a renewal is not merit reviewed, it is to be treated as a noncompetitive award.

Section 600.16(i) is being changed to substitute "reviewer" and "review" for "evaluator" and "evaluation" to conform to the terminology in the rest of § 600.16.

Section 600.31(d)(1) is changed to exclude SBIR awards from the provisions for automatic carryover applicable to all other research awards.

Section 600.31(f) is revised to exclude SBIR awards from the requirement that a single budget period not exceed 12 months.

Section 600.103(b)(6) is amended to exclude SBIR awards from the blanket waiver of prior approvals applicable to all other research awards.

In § 600.103(f)(1), "application" is being changed to "applicant".

Section 600.103(h) is amended to provide for the payment of a fee or profit to SBIR recipients.

Section 600.109(a) is amended to include a reference to an SBIR exception to some of the financial management requirements contained in § 600.125.

Sections 600.112 (a), (b), (c), (d), and (e) are revised to eliminate the provisions concerning letter of credit. The amended language continues to give primary status to advance payments to financial assistance recipients in conformance with the OMB Circulars. As a result of the new language, current Sections are redesignated as follows: § 600.112(e) is redesignated 600.112(f); § 600.112(f) is redesignated 600.112(g); § 600.112(g) is redesignated 600.112(h) and § 600.112(h) is redesignated 600.112(i).

In § 600.113(b), the reference to the Intergovernmental Cooperation Act of 1968 is deleted.

In § 600.113(e)(1), "ther" is being changed to "other".

Section 600.119(c)(1) is revised to specifically state that single bid or sole source procurements under research financial assistance do not have to be approved by the awarding agency, with the exception of SBIR recipients, which are covered by § 600.125(d)(2).

Section 600.119(d)(2) is changed to correct the reference concerning patents, inventions and copyrights. The proper citation is § 600.33, not 600.118.



Section 600.120 is amended by replacing the reference to Attachment F of OMB Circular A-110 with a reference to OMB Circular A-133.

Section 600.125 is added to codify the six previously published class deviations to the Rules applicable to the Small Business Innovation Research Program. Cross references to this section have been included in §§ 600.31(d)(1), 600.31(f), 600.103(b)(6), 600.103(h) and 600.109(a).

In § 600.420(a), "expand" is being changed to "expend".

In § 600.421(i), the references to the Intergovernmental Cooperation Act and the Indian Self-Determination Act are deleted.

In § 600.424(b)(7)(ii), "costs" in the second sentence is being changed to "cost".

In § 600.436(g)(2)(i), "seciton" is being changed to "section".

### III. Review Under Executive Order 12612

Executive Order 12612 requires that regulations, rules, legislation, and any other policy actions be reviewed for any substantial direct effects on States, on the relationship between the national government and the States, or in the distribution of power and responsibilities among various levels of government. If there are sufficient substantial direct effects, then the Executive Order requires preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action.

Today's proposed rule, when finalized, will revise certain policy and procedural requirements. However, the DOE has determined that none of the revisions will have a substantial direct effect on the institutional interests or traditional functions of States.

### IV. Review Under Executive Order 12291

Today's proposal was reviewed under Executive Order 12291. The DOE has concluded that the rule is not a "major rule" because its promulgation will not result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States based enterprises to compete in domestic or export markets. In accordance with requirements of the Executive Order, this rulemaking has been reviewed by the Office of Management and Budget (OMB)

### V. Review Under the Regulatory Flexibility Act

These proposed regulations were reviewed under the Regulatory Flexibility Act of 1980, Public Law 96-354, 94 Stat. 1164, which requires preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities; i.e., small businesses, small organizations, and small governmental jurisdictions. The DOE has concluded that the proposed rule would only affect small entities as they apply for and receive financial assistance and does not create additional economic impact on small entities. The DOE certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities and, therefore, no regulatory flexibility analysis has been prepared.

### VI. Review Under the Paperwork Reduction Act

No information collection or recordkeeping requirements are imposed upon the public by this proposed rulemaking. Accordingly, no OMB clearance is required under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulations at 5 CFR part 1320.

### VII. Review Under the National Environmental Policy Act

The DOE has concluded that promulgation of these rules clearly would not represent a major Federal action having significant impact on the human environment under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, *et seq.* (1976)), the Council on Environmental Quality Regulations (40 CFR parts 1500-1508), and the DOE guidelines (10 CFR part 1021) and, therefore, does not require an environmental impact statement pursuant to NEPA.

### VIII. Public Comments

Interested persons are invited to participate in this rulemaking by submitting data, views, or arguments with respect to the proposed changes set forth in this notice. Three copies of written comments should be submitted to the address indicated in the ADDRESSES section of this notice. All comments received will be available for public inspection in the DOE Reading Room, room 1E-190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, between the hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. All written comments received by

December 9, 1991 will be fully considered prior to publication of a final rule resulting from this proposal. Any information considered to be confidential must be so identified and submitted in writing, one copy only. The DOE reserves the right to determine the confidential status of the information and to treat it according to our determination.

The Department has concluded that this proposed rule does not involve a substantial issue of fact or law and that the proposed rule should not have substantial impact on the nation's economy or a large number of individuals or businesses. Therefore, pursuant to Public Law 95-91, the DOE Organization Act, and the Administrative Procedures Act (5 U.S.C. 553), the Department does not plan to hold a public hearing on this proposed rule.

### List of Subjects in 10 CFR Part 600

Administrative practice and procedure, Cooperative agreements/energy, Copyrights; Educational institutions; Energy; Grants/energy; Hospitals; Indian Tribal governments; Individuals; Inventions and patents; Non-profit organizations; Reporting requirements; and Small businesses.

In consideration of the foregoing, the Department of Energy hereby proposes to amend chapter II of title 10 of the Code of Federal Regulations by amending part 600 as set forth below.

Issued in Washington, DC October 31, 1991.  
Silas B. Fisher,

Director, Office of Procurement, Assistance, and Program Management.

For the reasons set out in the preamble, part 600 of chapter II, title 10 of the Code of Federal Regulations is proposed to be amended as follows:

### PART 600—FINANCIAL ASSISTANCE RULES

1. The authority citation for part 600 continues to read as follows:

Authority: Secs. 644 and 646, Pub. L. 95-91, 91 Stat. 599 (42 U.S.C. 7254 and 7256); Pub. L. 97-258, 96 Stat. 1003-1005 (31 U.S.C. 6301-6308), unless otherwise noted.

#### § 600.2 [Amended]

2. In § 600.2, paragraphs (c), (d), (e) and (f) are redesignated as (d), (e), (f) and (g) respectively, and a new paragraph (c) is added to read as follows:

\* \* \* \* \*

(c) A financial assistance recipient performing research, development, or related activities involving the use of human subjects shall comply with DOE



regulations in 10 CFR part 745 "Protection of Human Subjects" and any additional provisions which may be included in the Special Terms and Conditions of the award.

#### § 600.7 [Amended]

3. § 600.7(b)(2)(i)(G) is redesignated as (H) and a new (G) is added to read as follows:

- (b) \* \* \*
- (2) \* \* \*
- (i) \* \* \*
- (G) A specific recipient has been statutorily designated.

#### § 600.12 [Amended]

4. Section 600.12(c) is added as follows:

(c) Provision shall be made to design and construct all buildings, in which DOE funds are used, to meet appropriate seismic design and construction standards. Seismic codes and standards meeting or exceeding the provisions of the Uniform Building Code (1988 or as revised), shall be deemed appropriate.

5. Section 600.14 is amended by revising paragraphs (c) and (e)(1)(ii) and by adding a sentence to the end of paragraph (f) as follows:

#### § 600.14 Unsolicited applications.

(c) *Preparation and submission of application.* A guide for preparing unsolicited applications/proposals is available from the Field/Headquarters Support Division (PR-132), Office of Procurement, Assistance and Program Management, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

- (e) \* \* \*
- (1) \* \* \*
- (ii) The proposed project represents a unique or innovative idea, method, or approach which would not be eligible for financial assistance under a recent, current, or planned solicitation, and if, as determined by DOE, a competitive solicitation would be inappropriate.

(f) \* \* \* Such an explanation must address the selection criteria contained in § 600.14(e)(1) (i) and (ii).

6. Section 600.16 is amended by revising the heading and paragraph (a)(3)(ii) as set forth below. In addition, paragraph (i) is amended by changing "evaluators" to "reviewers", "evaluator"

to "reviewer", and "evaluation" to "review".

#### § 600.16 Objective merit review.

- (a) \* \* \*
- (3) \* \* \*
- (ii) For projects in which multiple renewals are probable, an objective merit review need not necessarily be done at each renewal, but instead at appropriate points during the course of the project. A determination that a project need not be reviewed at each renewal shall be made at the time the initial award is issued, or, in the event that unforeseen circumstances arise which preclude a merit review at a previously scheduled point during the course of a project, the merit review of a renewal application may be waived prior to the renewal of the project. The criteria on which the determination that a project need not be reviewed at each renewal is based, shall be included in the system of objective merit review to be established by the responsible official in accordance with paragraphs (a)(1) and (2) of this section. For a waiver to be issued, the project officer shall prepare, with the concurrence of his or her immediate supervisor, a written determination for the approval of the responsible official that a merit review is not appropriate at the particular point in time, setting forth the circumstances that preclude the merit review. The determination shall contain an evaluation of the technical merit of the project being proposed for additional support. This determination shall also set forth the facts which would support the justification required by 10 CFR 600.7(b)(2)(i). Finally, the determination shall indicate the reports required under the award and shall be placed in the official file by the Contracting Officer.

#### § 600.31 [Amended]

7. Section 600.31(d)(1) is revised, paragraph (f)(3) is amended by replacing the period at the end with ";or", and a new paragraph (f)(4) is added, to read as follows:

(d) *Extensions.* (1) Recipients of research awards, except recipients of SBIR awards (See § 600.125(d)), may extend the expiration date of the final budget period of the project (thereby extending the project period) if additional time beyond the established expiration date is needed to assure adequate completion of the original scope of work within the funds already made available. A single extension, which shall not exceed twelve (12)

months, may be made for this purpose, and must be made prior to the originally established expiration date. The recipient must notify the cognizant DOE Contracting Officer in the awarding office in writing within ten (10) days of making the extension.

(f)(3) \* \* \*; or

(4) The award is a Phase II SBIR award (see § 600.125(c)).

#### § 600.103 [Amended]

8. In § 600.103, paragraphs (b)(6) and (h) are revised to read as follows, and in paragraph (f)(1), "application" is changed to "applicant."

(b) \* \* \*

(6) Before a recipient may make changes in the following areas on research financial assistance awards, the written approval of the cognizant Contracting Officer at the DOE is required: (i) Changes in objectives or scope, (ii) temporary replacement or change of principal investigator or change of key personnel, and (iii) change of the institution to which the award is to be made. All other Federal prior approval requirements, including those in OMB Circulars A-21 and A-110, are waived for research, except as provided in § 600.125 for SBIR awards. The recipient may maintain such internal prior approval systems as it considers necessary.

(h) *Fee or profit.* No increment above cost may be paid to a grantee or subgrantee under a DOE grant or subgrant, except for SBIR recipients as provided in § 600.125(d)(3). A fee or profit may be paid to a contractor providing goods or services under a contract with a grantee or subgrantee.

#### § 600.109 [Amended]

9. Section 600.109(a) is revised to read as follows:

(a) *General.* Except as provided in paragraph (c) of this section and § 600.125 of this subpart, grantees and subgrantees shall have financial management systems which meet the minimum standards set forth in paragraph (b) of this section.

#### § 600.112 [Amended]

10. Section 600.112(a), (b), (c), and (d), are revised, paragraphs (e) through (h) are redesignated as paragraphs (f) through (i) and a new paragraph (e) is added. The revised and added paragraphs are set forth below.



**§ 600.112 Payment.**

(a) *Scope.* This section prescribes the basic standard and the methods under which the DOE will make payments to grantees, and grantees will make payments to subgrantees and contractors.

(b) *Basic standard.* Methods and procedures for payment shall minimize the time elapsing between the transfer of funds and disbursement by the grantee or subgrantee, in accordance with Treasury regulations at 31 CFR part 205.

(c) *Advances.* Grantees and subgrantees shall be paid in advance, provided that their financial management systems meet the standards for fund control and accountability specified in § 600.109(b), including procedures or planned procedures that will minimize the time elapsing between the transfer of the funds from the U.S. Treasury and their disbursement by the grantee or subgrantee, except as provided in 600.125(b)(5).

(d) *Reimbursement.* Reimbursement shall be the preferred method when the requirements in paragraph (c) of this section are not met. The DOE may also use the reimbursement method if the major portion of the project or activity will be financed by private financing or Federal loans, with the DOE grant representing 25 percent or less of the total cost.

(e) *Conversion from advance payment method.* The DOE may convert a grantee from advance payment to reimbursement whenever the grantee no longer meets the criteria for advance payment specified in paragraph (c) of this section. Any such conversion may be accomplished only after the DOE has advised the grantee in writing of the reasons for the proposed action and has provided a period of at least 30 days within which the grantee may take corrective action or provide satisfactory assurances of its intention to take such action.

**§ 600.113 [Amended]**

11. Section 600.113(b) is revised to read as follows, and in paragraph (e)(1) "ther" is corrected to read "other".

(b) *Income resulting from advances of DOE funds.* Unless there are statutory provisions to the contrary, a grantee shall remit to DOE any interest or other investment income earned on advances of DOE funds.

**§ 600.119 [Amended]**

12. In § 600.119, paragraphs (c)(1) and (d)(2) are revised to read as follows:

(c) *Prior approval requirements.* (1) A grantee or subgrantee must receive prior written approval from the awarding party before entering into any sole source contract or a contract where only one bid or proposal is received when the value of the contract is expected to exceed \$5,000 in the aggregate, and the grantee or subgrantee is not a State government, local government, Indian tribal government, SBIR award recipient (see § 600.125(d)(2)), or research award recipient.

(d) \* \* \*

(2) A clause requiring the contractor to comply with applicable DOE requirements concerning patents, inventions and copyrights (see § 600.33).

**§ 600.120 [Amended]**

13. In § 600.120, the introductory text to paragraph (c)(1) is revised as follows:

(c) *Nonprofit organizations.* (1) Except for public hospitals and public colleges and universities that are included in an audit conducted pursuant to Subpart D of this Part, all grantees and subgrantees that are institutions of higher education, hospitals or other nonprofit organizations shall comply with the requirements of OMB Circular A-133, and shall:

14. Section 600.125 is added as follows:

**§ 600.125 Special Provisions for Small Business Innovation Research Grants**

(a) *General.* This section contains provisions applicable to the Small Business Innovation Research (SBIR) Program. This codifies six class deviations pertaining to the SBIR program which were published in the Federal Register on May 22, 1990 (55 FR 21008).

(b) *Provisions Applicable to Phase I SBIR Awards.* Phase I SBIR awards may be made on a fixed obligation basis, subject to the following requirements:

(1) While proposed costs must be analyzed in detail to ensure consistency with applicable cost principles, incurred costs are not subject to regulation by the standards of cost allowability;

(2) Although detailed budgets are submitted by a recipient and reviewed by the DOE for purposes of establishing the amount to be awarded, budget categories are not stipulated in making an award;

(3) Prior approval from the DOE for rebudgeting among categories by the recipient is not required. Prior approval from the DOE is required for situation involving sole source or single bid procurements as provided in § 600.125(d)(2). Prior approval from the DOE is also required for any variation from the requirement that no more than one-third of Phase I work can be done by sub-contractors or consortium partners (See Paragraph 6.c. of Small Business Innovation Research Policy Directive, 53 FR 23829, June 24, 1988);

(4) Pre-award expenditure approval is not required;

(5) Payments are to be made in the same manner as other financial assistance (see § 600.112), except that, when determined appropriate by the cognizant program official and contracting officer, a lump sum payment may be made. If a lump sum payment is made, the award must be conditioned to require the recipient to return to the DOE amounts remaining unexpended at the end of the project if those amounts exceed \$500;

(6) Recipients will certify in writing to the Contracting Officer at the end of the project that the activity was completed or the level of effort was expended. Should the activity or effort not be carried out, the recipient would be expected to make appropriate reimbursements;

(7) Requirements for periodic reports may be established for each award so long as they are consistent with § 600.115;

(8) Changes in principal investigator or project leader, scope of effort, or institution, require the prior approval of the DOE.

(c) *Provision Applicable to Phase II SBIR Awards.* Phase II SBIR awards may be made for a single budget period 24 months.

(d) *Provisions Applicable to Phase I and Phase II SBIR Awards.*

(1) The prior approval of the cognizant DOE Contracting Officer is required before the final budget period of the project period may be extended without additional funds.

(2) A grantee or subgrantee must receive the prior written approval of the awarding party before entering into any sole source contract or a contract where only one bid or proposal is received when the value of the contract is expected to exceed \$25,000 in the aggregate.

(3) A fee or profit may be paid to SBIR recipients.



**§ 600.420 [Amended]**

15. In the first sentence of § 600.420(a), "expand" is corrected to read "expend".

16. Section 600.421(i) is revised to read as follows:

**§ 60.421 [Amended]**

\* \* \* \* \*

**(i) Interest earned on advances.**

Unless there are statutory provisions the contrary, grantees and subgrantees shall promptly, but at least quarterly, remit to the Federal agency interest earned on advances. The grantee or subgrantee may keep interest amounts up to \$100 per year for administrative expenses.

**§ 600.424 [Amended]**

17. In the second sentence of § 600.424(b)(7)(ii) "costs" is corrected to read "cost".

**§ 600.436 [Amended]**

18. In § 600.436(g)(2)(i), "seciton" is corrected to read "section".

[FR Doc. 91-26789 Filed 11-6-91; 8:45 am]

BILLING CODE 6450-01-M

**FEDERAL RESERVE SYSTEM****12 CFR Parts 208 and 225**

[Docket No. R-0740]

**[Regulation H, Regulation Y; Capital; Capital Adequacy Guidelines]**

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Notice of Proposed Revisions to Capital Adequacy Guidelines.

**SUMMARY:** The Board is proposing to remove the limit on the amount of noncumulative perpetual preferred stock bank holding companies may include in Tier 1 capital. Cumulative perpetual preferred stock would continue to be included in Tier 1 capital for bank holding companies, up to a limit of 25 percent of Tier 1 capital.

**DATES:** Comments on the proposed revisions to the Federal Reserve Board's risk-based capital guidelines and leverage capital guidelines should be submitted on or before November 22, 1991.

**ADDRESSES:** Comments, which should refer to docket No. R-0740, may be mailed to Mr. William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenues, NW., Washington, DC 20551; or delivered to room B-2223, Eccles Building, between 8:45 a.m. and 5:15 p.m. weekdays. Comments may be inspected in room B-1122 between 9 a.m. and 5 p.m. weekdays, except as provided in § 2612.8 of the Board's Rules Regarding

Availability of Information, 12 CFR 261.8.

**FOR FURTHER INFORMATION CONTACT:**

Roger T. Cole, Assistant Director (202/452-2618), Rhoger H. Pugh, Manager (202/728-5883), Norah M. Barger, Supervisory Financial Analyst (202/452-2402), Robert E. Motyka, Senior Financial Analyst (202/452-3621), Division of Banking Supervision and Regulation; and Michael J. O'Rourke, Senior Attorney (202/452-3288), Legal Division. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), Dorothea Thompson (202/452-3544).

**SUPPLEMENTARY INFORMATION:****I. Background**

The international bank capital standards (Basle Accord)<sup>1</sup> allow banks to include noncumulative perpetual preferred stock place in Tier 1 capital and place no formal limit on the amount of such instruments that may be included in Tier 1.<sup>2</sup> The Basle framework, which by its terms applies only to internationally active banks, was adopted by the Federal Reserve for state nonmember banks. In addition, the Board chose to apply a risk-based capital framework similar to the Basle Accord to U.S. bank holding companies generally on a consolidated basis.<sup>3</sup> Under the Federal Reserve's bank holding company capital guidelines, holding companies are allowed to include both noncumulative and cumulative perpetual preferred stock in Tier 1 capital, but the total of all perpetual preferred stock includable in Tier 1 capital is limited to 25 percent of Tier 1.<sup>4</sup> Amounts of such stock in excess

<sup>1</sup>The Basle Accord is a risk-based capital framework that was proposed by the Basle Committee on Banking Regulations and Supervisory Practices and endorsed by the central bank governors of the Group of Ten (G-10) countries in July 1988. The Committee is comprised of representatives of the central banks and supervisory authorities from the G-10 countries (Belgium, Canada, France, Germany, Italy, Japan, Netherlands, Sweden, Switzerland, the United Kingdom, and the United States) and Luxembourg.

<sup>2</sup>Noncumulative perpetual preferred stock is perpetual preferred stock whose dividends, if missed, do not accrue and will never be paid. Cumulative perpetual preferred stock is preferred stock whose dividends, if missed because of insufficient earnings or any other reason, accumulate until all arrearages are paid out. Cumulative preferred dividends have preference over common dividends, which cannot be paid out as long as any cumulative preferred dividends remain unpaid.

<sup>3</sup>For bank holding companies with consolidated assets of less than \$150 million in assets, the risk-based capital guidelines generally are applied on a bank-only basis.

<sup>4</sup>Under the risk-based capital guidelines, certain types of perpetual preferred stock do not qualify for

of the limitation may be included in Tier 2 capital. The limit on preferred stock is consistent with the Board's long-standing view that common equity should remain the dominant form of a banking organization's capital structure.

A principal reason for the Board's decision to limit the amount of perpetual preferred stock in bank holding Tier 1 capital is the fact that cumulative preferred, the type of perpetual preferred most prevalent in U.S. financial markets, normally involves preset dividends that cannot be cancelled, but only deferred. An institution that passes dividends on cumulative preferred stock must pay off any accumulated arrearages before it can resume payment of its common stock dividends. Thus, undue reliance on cumulative perpetual preferred stock and the related possibility of large dividend arrearages could complicate an organization's ability to raise new common equity in times of financial difficulty. On the other hand, dividends on noncumulative preferred, like dividends on common stock, may be cancelled. Thus, with respect to dividends, noncumulative preferred stock has characteristics that are consistent with common stock, the principal component of Tier 1 capital.

Conditions in the banking industry underscore the desirability of affording banking organizations greater flexibility in raising capital. This can assist organizations in strengthening their capital positions and expanding their ability to extend credit to sound borrowers. In view of these considerations, the Board is proposing to lift the limit on the amount of noncumulative preferred stock that bank holding companies may include in Tier 1 capital. This proposal is consistent with other steps initiated by the Federal bank regulatory agencies, in conjunction with the Treasury Department, to address concerns relating to the availability of credit to sound borrowers.

**II. Proposal**

The Board is proposing to remove the limit on the amount of noncumulative perpetual preferred stock a bank holding company may include in its Tier 1 capital. Cumulative perpetual preferred stock would continue to be included in Tier 1 capital for bank holding companies, up to a limit of 25 percent of Tier 1 capital.

inclusion in Tier 1 capital. For example, perpetual preferred stock in which the dividend is reset periodically based, in whole or in part, upon the banking organization's credit standing is excluded from Tier 1 capital, but may be included in Tier 2 capital.



By removing the limit for noncumulative perpetual preferred stock, this proposal will achieve parity with regard to the treatment of noncumulative perpetual preferred stock between the U.S. risk-based capital guidelines for bank holding companies and the Basle framework for banks. Thus, the proposal will place U.S. bank holding companies on a more equal footing with foreign banks subject to the Basle Accord with regard to their ability to augment Tier 1 capital through the issuance of noncumulative perpetual preferred stock. The additional flexibility provided by this step may assist bank holding companies to strengthen their capital positions and expand their lending capacity.

Although the Board is proposing to lift the limit on noncumulative perpetual preferred stock, it continues to believe that bank holding companies should avoid overreliance on preferred stock within Tier 1 capital. In proposing this step, the Board notes that the capital structure of a bank holding company is subject to quarterly review (through the analysis of financial reports filed with the Federal Reserve), and the composition of an organization's capital base and its capital plans are subject to in-depth assessment during annual inspections and as part of the Federal Reserve's consideration of applications. The language of the Federal Reserve's risk-based capital guidelines makes clear the Board's long-standing belief that banking organizations should avoid overreliance on nonvoting equity instruments, including preferred stock, in Tier 1 capital. Capital structures that are inconsistent with this principle may result in supervisory or enforcement actions, including possible denial of applications filed with the Federal Reserve. In addition, rating agencies take the amount of common equity and preferred stock an organization has, as well as the overall composition of the organization's core capital, into account in determining the organization's financial ratings. Thus, there are a number of mechanisms in place to monitor banking organizations' use of preferred stock and to discourage undue reliance on such instruments.

### III. Regulatory Flexibility Act Analysis

The Federal Reserve Board does not believe adoption of this proposal would have a significant economic impact on a substantial number of small business entities (in this case, small banking organizations), in accord with the spirit and purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). In addition, because the risk-based and leverage capital guidelines generally do

not apply to bank holding companies with consolidated assets of less than \$150 million, this proposal will not affect such companies.

### List of Subjects

#### 12 CFR Part 208

Accounting, Agricultural loan losses, Applications, Appraisals, Banks, Banking, Branches, Capital adequacy, Confidential business information, Currency, Dividend payments, Federal Reserve System, Flood insurance, Publication of reports of condition, Reporting and recordkeeping requirements, Securities, State member banks.

#### 12 CFR Part 225

Administrative practice and procedure, Appraisals, Banks, Banking, Capital adequacy, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities, State member banks.

For the reasons set forth in this notice, and pursuant to the Board's authority under section 5(b) of the Bank Holding Company Act of 1956 (12 U.S.C. 1844(b)), and section 910 of the International Lending Supervision Act of 1983 (12 U.S.C. 3909), the Board is amending 12 CFR parts 208 and 225 to read as follows:

### PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM

1. The authority citation for part 208 continues to read as follows:

Authority: Sections 9, 11(a), 11(c), 19, 21, 25, and 25(a) of the Federal Reserve Act, as amended (12 U.S.C. 321-338, 248(a), 248(c), 461, 481-486, 601, and 611, respectively); sections 4 and 13(j) of the Federal Deposit Insurance Act, as amended (12 U.S.C. 1814 and 1823(j), respectively); section 7(a) of the International Banking Act of 1978 (12 U.S.C. 3105); sections 907-910 of the International Lending Supervision Act of 1983 (12 U.S.C. 3906-3909); sections 2, 12(b), 12(g), 12(i), 15B(c) (5), 17, 17A, and 23 of the Securities Exchange Act of 1934 (15 U.S.C. 78b, 78(b), 78(g), 78(i), 78o-4(c) (5), 78q, 78q-1, and 78w, respectively); section 5155 of the Revised Statutes (12 U.S.C. 36) as amended by the McFadden Act of 1927; and sections 1101-1122 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989 (12 U.S.C. 3310 and 3331-3351).

### Appendix A—[Amended]

2. In Appendix A, the footnote designator in the text is removed and footnote 6 is removed and reserved.

### PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL

1. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j) (13), 1818, 1831i, 1843(c) (8), 1844(b), 3106, 3108, 3907, 3909, 3310, and 3331-3351.

### Appendix A—[Amended]

2. Appendix A is amended by revising paragraphs (ii) and (iii) and adding paragraph (iv) in II.A.1., and by revising the last three sentences in the third paragraph and the entire fourth paragraph in II.A.1.b., to read as follows:

\* \* \* \* \*

II. \* \* \*

A. \* \* \*

1. \* \* \*

(i) \* \* \*

(ii) qualifying noncumulative perpetual preferred stock (including related surplus).

(iii) qualifying cumulative perpetual preferred stock (including related surplus), subject to certain limitations described below.

(iv) minority interest in the equity accounts of consolidated subsidiaries.

\* \* \* \* \*

b. \* \* \* \* \*

However, the aggregate amount of cumulative perpetual preferred stock that may be included in a holding company's tier 1 is limited to one-third of the sum of core capital elements, excluding the cumulative perpetual preferred stock (that is, items i, ii, and iv above). Stated differently, the aggregate amount may not exceed 25 percent of the sum of all core capital elements, including cumulative perpetual preferred stock (that is, items i, ii, iii, and iv above). Any cumulative perpetual preferred stock outstanding in excess of this limit may be included in tier 2 capital without any sublimits within that tier (see discussion below).

While the guidelines allow for the inclusion of noncumulative perpetual preferred stock and limited amounts of cumulative perpetual preferred stock in tier 1, it is desirable from a supervisory standpoint that voting common equity remain the dominant form of tier 1 capital. Thus, bank holding companies should avoid overreliance on preferred stock or nonvoting equity elements within tier \* \* \* \* \*



**Appendix D—[Amended]**

3. Appendix D is amended by revising the first two sentences in footnote 3 to read as follows:

II. \*\*\*

<sup>2</sup>At the end of 1992, Tier 1 capital for bank holding companies includes common equity, minority interest in the equity accounts of consolidated subsidiaries, qualifying noncumulative perpetual preferred stock, and qualifying cumulative perpetual preferred stock. (Cumulative perpetual preferred stock is limited to 25 percent of Tier 1 capital.) \*\*\*

Board of Governors of the Federal Reserve System, October 31, 1991.

William W. Wiles,

Secretary of the Board.

[FR Doc. 91-26716 Filed 11-6-91; 8:45 am]

BILLING CODE 6210-01-F

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 71**

[Airspace Docket No. 91-AEA-21]

**Proposed Alteration of Control Zone; Rome, NY**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The FAA is proposing to modify the Rome, NY, Control Zone. This proposed modification is in response to a request from the U.S. Department of the Air Force. The intended effect of this proposed action is to ensure segregation of aircraft operating under instrument procedures to and from Griffiss Air Force base (AFB), Rome, NY, from other aircraft operating under visual weather conditions in controlled airspace.

**DATES:** Comments must be received on or before December 2, 1991.

**ADDRESSES:** Send comments on the rule in triplicate to:

George Dodelin, Manager, System Management Branch, AEA-530, Docket No. 91-AEA-21, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430.

The official docket may be examined in the Office of the Assistant Chief Counsel, AEA-7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours

in the System Management Branch, AEA-530, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

**FOR FURTHER INFORMATION CONTACT:** Mr. Curtis L. Brewington, Airspace Specialist, System Management Branch, AEA-530, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone: (718) 917-0857.

**SUPPLEMENTARY INFORMATION:****Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made:

"Comments to Airspace Docket No. 91-AEA-21". The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

**Availability of NPRMs**

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA-7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11-2A which describes the application procedure.

**The Proposal**

The FAA is considering an amendment to § 71.171 of part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Rome, NY, Control Zone, as per a request from the U.S. Department of the Air Force. This action would provide greater segregation of aircraft operating under instrument procedures from other aircraft operating under visual weather conditions in controlled airspace. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6G dated September 4, 1990.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 71**

Aviation safety, Control zones.

**The Proposed Amendment**

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

**PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS**

1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. App. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

**§ 71.171 [Amended]**

2. Section 71.171 is amended as follows:

**Rome, NY [Revised]**

Griffiss AFB, Rome, NY (lat. 43°13'58"N., long. 75°25'W.)

Within a 5-mile radius of Griffiss AFB, Rome, NY and within 2 miles each side of a



314° (T) 327° (M) bearing extending from the 5-mile radius to 9 miles northwest of the airport and within 2 miles each side of a 134° (T) 147° (M) bearing extending from the 5-mile radius to 9 miles southeast of the airport.

Gary W. Tucker,

Manager, Air Traffic Division.

[FR Doc. 91-26869 Filed 11-6-91; 8:45 am]

BILLING CODE 4910-13-M

#### 14 CFR Part 71

[Airspace Docket No. 91-ASO-22]

#### Proposed Establishment of Transition Area, Blairsville, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to establish the Blairsville, GA, Transition Area. A standard instrument approach procedure (SIAP) has been developed to serve the Blairsville Airport. This proposed action would lower the base of controlled airspace from 1200 feet to 700 feet above the surface in vicinity of the airport. The additional controlled airspace of the transition area would provide protection of instrument flight rules (IFR) aeronautical operations. If approved, the operating status of the Blairsville Airport will be changed from visual flight rules (VFR) operations only to include IFR operations concurrent with publication of the SIAP.

**DATES:** Comments must be received on or before: December 30, 1991.

**ADDRESSES:** Send comments on the proposal in triplicate to:

Federal Aviation Administration,  
Docket No. 91-ASO-22, Manager,  
System Management Branch, ASO-530, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Assistant Chief Counsel for Southern Region, room 652, 3400 Norman Berry Drive, East Point, Georgia 30344; telephone (404) 763-7646.

**FOR FURTHER INFORMATION CONTACT:** James G. Walters, Airspace Section, System Management Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 763-7646.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions

presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the proposal.

Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 91-ASO-22." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, room 652, 3400 Norman Berry Drive, East Point, Georgia 30344, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

##### Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, System Management Branch (ASO-530), Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A which describes the application procedure.

##### The Proposal

The FAA is considering an amendment to § 71.181 of part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish the Blairsville, GA, Transition Area. A standard instrument approach procedure has been developed to serve the Blairsville Airport. This action would lower the base of controlled airspace from 1200 feet to 700 feet above the surface in vicinity of the airport. The additional controlled airspace of the transition area would provide protection of IFR aeronautical operations. If approved, the operating status of the airport will change from VFR operations only to include IFR

operations concurrent with publication of the SIAP. Section 71.181 of part 71 of the Federal Aviation Regulations was republished in FAA Order 7400.6G dated September 4, 1990.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

##### List of Subjects in 14 CFR Part 71

Aviation safety, Transition area.

##### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

#### PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. App. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Public Law 97-449, January 12, 1983); 14 CFR 11.69.

##### § 71.181 [Amended]

##### Blairsville, GA [New]

That airspace extending upward from 700 feet above the surface within a 2.5-mile radius of Blairsville Airport (lat. 34°51'18"N, long. 83°59'49"W); within 2.5 miles each side of the 323° bearing from the airport to a point of 10.5 miles northwest of the airport.

Issued in East Point, Georgia, on October 29, 1991.

Don Cass,

Acting Manager, Air Traffic Division,  
Southern Region.

[FR Doc. 91-26870 Filed 11-6-91; 8:45 am]

BILLING CODE 4910-13-M



## DEPARTMENT OF COMMERCE

## Technology Administration

## 15 CFR Part 1150

[Docket No. 910931-1231]

RIN 0692-AA11

## Marking of Toy, Look-Alike and Imitation Firearms

AGENCY: Technology Administration, Commerce.

ACTION: Notice of proposed rulemaking; request for comments.

**SUMMARY:** The Under Secretary for Technology, United States Department of Commerce, requests comments on proposed changes to regulations found at 15 CFR part 1150 pertaining to marking requirements for toy, look-alike and imitation firearms. Part 1150 was promulgated in May of 1989, and implements section 4 of the Federal Energy Management Improvement Act of 1988 ("Act") (Pub. L. 100-615) which prohibits the manufacturing, entering into commerce, shipping, transporting, or receipt of any toy, imitation or look-alike firearm ("device") unless such device contains, or has affixed to it, a marking approved by the Secretary of Commerce. The proposed revision sets out additional permissible markings, and further defines those devices covered by the regulation.

**DATES:** Comments on the proposed revisions must be received no later than January 6, 1992.

**ADDRESSES:** United States Department of Commerce, room 4410, Washington, DC 20230.

**FOR FURTHER INFORMATION CONTACT:** James V. Lacy, Chief Counsel for Technology, telephone number (202) 377-1984, FAX (202) 377-0253.

**SUPPLEMENTARY INFORMATION:****Background**

Section 4(a) of the Federal Energy Management Improvement Act of 1988 provides that "it shall be unlawful for any person to manufacture, enter into commerce, ship, transport, or receive any toy, look-alike, or imitation firearm unless such firearm contains, or has affixed to it a marking approved by the Secretary of Commerce \* \* \*." (15 U.S.C. 5001(a)). Section 4(b)(1) of the Act establishes as an initial acceptable marking a permanently affixed, blaze orange plug inserted in the barrel of the toy, look-alike, or imitation firearm, recessed no more than 6 millimeters from the muzzle end of the barrel, and made an integral part of the device. (15 U.S.C. 5001(b)(1)). Section 4(b)(2)

authorizes the Secretary to approve an alternative marking for any toy, look-alike, or imitation firearm not capable of being marked with the requisite blaze orange plug, and to waive the marking requirements for any toy, look-alike, or imitation firearm that will only be used in the theatrical, movie or television industries. (15 U.S.C. 5001(b)(2)). Section 4(b)(3) authorizes the Secretary to adjust or change the marking system established pursuant to sections 4(b)(1) and (2), after consultation with interested persons. (15 U.S.C. 5001(b)(3)).

The regulation found at 15 CFR part 1150 maintained the blaze orange plug marking established by section 4(b)(1) of the Act and established as an alternative marking system for water guns, air-soft guns, light emitting guns or other ejecting toy, look-alike or imitation firearms which, as such, cannot be marked with a plug in the muzzle end of the barrel because it would restrict the opening necessary to discharge such things as water, nonmetallic projectiles, and light, a blaze orange marking permanently affixed to the exterior surface of the barrel and covering the circumference of the barrel and extending from the muzzle end for a depth of at least 6 millimeters. The regulation also established three other methods of marking for use in the alternative irrespective of whether the device could be marked with the blaze orange plug or blaze orange muzzle marking. The three alternatives were to mark the device at manufacture by: (1) Constructing it entirely of transparent or translucent materials which permit unmistakable observation of the device's complete contents; (2) permanently coloring the entire exterior surface of the device bright red, bright orange, bright yellow, bright green, or bright blue, either singly or as the predominant color in combination with other colors in any pattern; or (3) permanently coloring the entire exterior surface of the device predominantly in white in combination with one or more of the colors bright red, bright orange, bright yellow, bright green, or bright blue in any pattern. These alternatives were selected because they represent standard industry practice for most toy, look-alike and imitation firearms and, in the opinion of those consulted, are sufficient to identify the device as a toy, look-alike, or imitation firearm rather than as a real firearm.

**Description and Explanation of Proposed Changes**

Seven changes to part 1150 are being proposed in this notice:

First, § 1150.1 is proposed to be amended by restating the applicability of the regulation to be to devices which have the "appearance, shape, and/or configuration of a firearm"; as originally promulgated, the regulation applied to devices having the "general appearance, shape, and/or configuration of a firearm." This change is proposed to remove ambiguity from the regulation. The word "toy" which appears in line ten(10) of this section is deleted so as to conform with 15 U.S.C. 5001.

Second, "collector replica" has been defined in order to distinguish between replicas which are intended to be collectable reproductions and imitation firearms modelled after antique firearms but not intended to be used as a collector replica. The distinction is made because collector replicas are specifically exempt under the regulation whereas toy, look-alike or imitation firearms which are not intended to be used as collector replicas must meet the requirements of the regulation.

Third, an exception has been made in § 1150.1 to clarify that part 1150 does not apply to "decorative, ornamental, and miniature objects having the appearance, shape and/or configuration of a firearm, including those intended to be displayed on a desk or worn on bracelets, necklaces, key chains, and so on, provided that the miniatures measure no more than thirty-eight (38) millimeters in height by seventy (70) millimeters in length." This change is proposed to remove certain imitation firearms from the coverage of the rule because they are so small in size that they could not be mistaken for real firearms. These particular dimensions have been selected because the Technology Administration has not identified any firearms of lesser size that are capable of functioning as a real gun. Metric units are used to conform with the Metric Conversion Act.

Fourth, changes to § 1150.3 (a) and (b) allow the approved marking to be either "blaze orange" (Federal Standard 595a, February, 1987, color number 12199, issued by the General Services Administration) or an orange color brighter than that specified by the Federal Standard color number. This change is proposed to prevent enforcement actions involving goods that have bright orange markings in keeping with the intent of the regulation, but do not meet the exact standard for "blaze orange."

Fifth, a change to § 1150.3(b) removes the requirement that the imitation gun have an opening used to discharge water, nonmetallic projectiles, or light to get approval for a collar-type marking



(§ 1150.3(b)). With the proposed change, whether or not the gun emits light, water, etc., the collar-type marking will be available.

Sixth, several alternative markings are proposed to be added to the list of approved alternative markings, including coloration of the entire exterior surface in white, bright pink or bright purple. These additional colors are deemed bright enough that their inclusion in the approved markings list is appropriate. The alternative markings provision is also clarified to include colorations of the entire surface singly or in combinations of the approved colors. Section 1150.3 (e) is therefore deleted in order to eliminate redundancy.

Finally, the provisions found in § 1150.4 waiving part 1150 for any toy, look-alike or imitation firearm that will be used only in the theatrical, movie or television industries are proposed to be amended by creating an administrative mechanism for the processing of waiver requests. The proposed change requires that requests for waivers be made, in writing, to the Chief Counsel for Technology, United States Department of Commerce, and that the request must include a sworn affidavit which states with specificity the factual circumstances, and that the toy, look-alike or imitation firearm will be used only in the theatrical, movie or television industry. It is anticipated that such a statement would include the place of manufacture, and a discussion of the specific use and disposition of the items. As originally promulgated, part 1150 contained a self-enforcing waiver provision. This approach, however, has proven impractical since, absent a written waiver, imports of noncompliant toy, look-alike and imitation firearms are routinely prevented at the port of entry by the U.S. Customs Service. The proposed formal process would overcome this problem.

#### Request for Comments

The Under Secretary for Technology, United States Department of Commerce, requests comments on proposed changes to regulations found at 15 CFR part 1150 pertaining to marking requirements for toy, look-alike and imitation firearms.

Persons interested in commenting on the proposed regulations should submit their comments in writing to the above address. All comments received in response to this notice will become part of the public record and will be available for inspection and copying at the Department of Commerce Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover

Building, 14th and Constitution Ave., NW., Washington, DC 20230.

#### Additional Information

##### Executive Order 12291

The Under Secretary for Technology has determined that this rule is not a major rule within the meaning of section 1(b) of Executive Order 12291 because it will not result in:

- (1) An annual effect on the economy of \$100 million or more;
- (2) A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or,
- (3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Therefore, preparation of a Regulatory Impact Analysis is not required under Executive Order 12291.

##### Executive Order 12612

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

##### Executive Order 12372

This rule does not involve Federal financial assistance, direct Federal development, or the payment of any matching funds from a state or local government. Accordingly, the requirements of Executive Order 12372 are not applicable to this rule.

##### Regulatory Flexibility Act

The General Counsel of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that if this proposed rule is adopted, it would not have a significant economic impact on a substantial number of small entities because the alternative markings conform to existing industry practices for most toy, look-alike, and imitation firearms, thus reducing the rule's impact to only where such practices are not followed. As a result, a Regulatory Flexibility Analysis is not required to be prepared under the Regulatory Flexibility Act.

##### Paperwork Reduction Act

This rule does not contain information collection requirements subject to the Paperwork Reduction Act.

##### National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment

or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

#### List of Subjects in 15 CFR Part 1150

Business and industry, Commerce, Exports, Freight, Hobbies, Imports, Incorporation by reference, Labeling, Shipping, Toys, Transportation.

Robert M. White,  
*Under Secretary for Technology.*

For reasons set forth in the preamble, title 15, part 1150 of the Code of Federal Regulations is proposed to be amended as follows:

#### PART 1150—MARKING OF TOY, LOOK-ALIKE AND IMITATION FIREARMS

1. The authority citation for part 1150 continues to read as follows:

**Authority:** Section 4 of the Federal Energy Management Improvement Act of 1968, 15 U.S.C. 5001.

2. Section 1150.1 is revised to read as follows:

##### § 1150.1 Applicability.

This part applies to toy, look-alike and imitation firearms ("devices") having the appearance, shape, and/or configuration of a firearm and produced or manufactured and entered into commerce on or after May 5, 1989, including devices modelled on real firearms manufactured, designed, and produced since 1898. This part does not apply to:

(a) Non-firing collector replica antique firearms, which look authentic and may be a scale model but are not intended as toys modelled on real firearms designed, manufactured, and produced prior to 1898;

(b) Traditional B-B, paint-ball, or pellet-firing air guns that expel a projectile through the force of compressed air, compressed gas or mechanical spring action, or any combination thereof, as described in American Society for Testing and Materials standard F 599-85, Standard Consumer Safety Specification for Non-Powder Guns, June 28, 1985. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103. Copies may be inspected at the office of the Associate Director for Industry and Standards, National Institute for Standards and Technology, Gaithersburg, Maryland, or



at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC; and

(c) Decorative, ornamental, and miniature objects having the appearance, shape and/or configuration of a firearm, including those intended to be displayed on a desk or worn on bracelets, necklaces, key chains, and so on, provided that the miniatures measure no more than thirty-eight (38) millimeters in height by seventy (70) millimeters in length.

3. Section 1150.3 is amended by removing paragraph (e) and by revising paragraphs (a), (b), (d) to read as follows:

#### § 1150.3 Approved markings.

The following markings are approved by the Secretary of Commerce:

(a) A blaze orange (Federal Standard 595a, February, 1987, color number 12199, issued by the General Services Administration) or orange color brighter than that specified by the federal standard color number, solid plug permanently affixed to the muzzle end of the barrel as an integral part of the entire device and recessed no more than 6 millimeters from the muzzle end of the barrel. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of Federal Standard 595a may be obtained from the Office of Engineering and Technical Management, Chemical Technology Division, Paints Branch, General Services Administration, Washington DC 30406. Copies may be inspected at the office of the Associate Director for Industry and Standards, National Institute for Standards and Technology, Gaithersburg, Maryland, or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington DC.

(b) A blaze orange (Federal Standard 595a, February, 1987, color number 12199, issued by the General Services Administration) or orange color brighter than that specified by the Federal standard color number, marking permanently affixed to the exterior surface of the barrel, covering the circumference of the barrel from the muzzle end for a depth of at least 6 millimeters. This incorporation by reference was approved by the Director for the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of Federal Standard 595a may be obtained from the Office of Engineering and Technical Management, Chemical Technology Division, Paints Branch, General Services Administration, Washington DC 30406. Copies may be inspected at the office of the Associate

Director for Industry and Standards, National Institute for Standards and Technology, Gaithersburg, Maryland, or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington DC.

(c) \* \* \*

(d) Coloration of the entire exterior surface of the device in white, bright red, bright orange, bright yellow, bright green, bright blue, bright pink, or bright purple, either singly or in combinations of these colors in any pattern.

4. Section 1150.4 is revised to read as follows:

#### § 1150.4 Waiver.

The prohibitions set forth in § 1150.2 of this part may be waived for any toy, look-alike or imitation firearm that will be used only in the theatrical, movie or television industries. A request for such a waiver should be made, in writing, to the Chief Counsel for Technology, United States Department of Commerce, Washington, DC 20230. The request must include a sworn affidavit which states with specificity the factual circumstances, and that the toy, look-alike or imitation firearm will be used only in the theatrical, movie or television industry. A sample of the item must be included with the request.

[FR Doc. 91-26948 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-18-M

## POSTAL RATE COMMISSION

### 39 CFR Part 3001

[Docket No. RM91-1]

#### Rules of Practice and Procedure

**AGENCY:** Postal Rate Commission.

**ACTION:** Proposed rulemaking; addition to rulemaking record.

**SUMMARY:** The Commission has solicited suggestions for improvements in its rules of practice. 56 FR 28850 (June 25, 1991). The Commission is adding a recently issued Institute of Public Administration report on the ratemaking process to the rulemaking record. It is also (i) inviting public comment on the report; (ii) making copies available for review; and (iii) allowing supplementation of previous filings.

**DATES:** The Commission anticipates no change in the previously established December 30, 1991 deadline for comments.

**ADDRESSES:** Comments and correspondence should be sent to Charles L. Clapp, Secretary of the Commission, suite 300, 1333 H Street

NW., Washington, DC 20268-0001 (telephone: (202) 789-6840).

**FOR FURTHER INFORMATION CONTACT:** David F. Stover, General Counsel, at the above address (telephone: (202) 789-6820).

**SUPPLEMENTARY INFORMATION:** The Commission is in receipt of the October 1991 Report to the Board of the Governors of the Postal Service submitted by the Institute of Public Administration (IPA) on "The Ratemaking Process and the Postal Service." This report, which was prepared by IPA under contract to the Postal Service, contains discussion, findings, and recommendations about the ratemaking process.

The Commission has determined that the topics addressed in the IPA Report make it an appropriate addition to the rulemaking record. Copies of the report will be available for review in the Commission's docket room. The Commission invites interested parties to comment on the bearing of the report's findings and recommendations on matters under consideration in this proceeding. The Commission anticipates no change in the December 30, 1991 deadline, but notes that parties who have submitted comments may supplement them, as of right, in light of this addition to the record.

Issued by the Commission on November 1, 1991.

Charles L. Clapp,

Secretary.

[FR Doc. 91-26925 Filed 11-6-91; 8:45 am]

BILLING CODE 7710-FW-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 80

[PR Docket No. 91-293; FCC 91-314]

**Amendment of Part 80 of the Commission's Rules to Permit the Use of Facsimile and Data Emissions on Marine Public Correspondence Channels in the 156-162 MHz Band**

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This Notice of Proposed Rule Making (Notice) proposes to permit the use of facsimile and data communications nationwide on all marine 156-162 MHz band (marine VHF) public correspondence channels for communications between public coast stations and ship stations. This notice responds to a request by WJG Maritel



Corporation (WJG) to permit such use. The effect of the proposed action is to provide VHF public coast stations and the commercial and noncommercial vessels they serve with a wider range of communications options such as facsimile, teleprinter, and data communications and to promote more efficient use of the frequency spectrum.

**DATES:** Comments are due on or before December 16, 1991; and reply comments on or before January 2, 1992.

**ADDRESSES:** Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** J. Joy Alford, Aviation & Marine Branch, Private Radio Bureau, (202) 632-7175.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Notice of Proposed Rule Making, adopted October 2, 1991, and released October 23, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC 20554. The Complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1114 21st Street, NW., Washington, DC 20036.

#### Summary of Notice of Proposed Rule Making

1. Since 1986, an integrated system of public coast stations operating on the marine VHF public correspondence channels in the Great Lakes region has been permitted to provide facsimile and data communication services to ship stations. Individual public coast stations operating on the same channels in other parts of the United States have been limited to voice only operations. This proposed action will permit the additional use of facsimile and data communications on public correspondence channels in the frequency band 156-162 MHz (marine VHF) by all public coast stations. The Bureau recommends adoption of the Notice of Proposed Rule Making which proposes to expand the range of communications services that marine VHF public coast stations may offer to include facsimile and data communications.

#### Procedural Matters

##### *Ex Parte Rules—Non-Restricted Proceeding*

2. This is a non-restricted notice and comment rule making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda

period, provided they are discussed as provided in Commission rules. See generally 47 CFR 1.1202, 1.1203 and 1.1206(a).

#### Comment Dates

3. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before December 16, 1991 and reply comments on or before January 2, 1992. To file formally in this proceeding, you must file an original and five copies of all comments, reply comments, and supporting documents. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comments and reply comments to Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the Dockets Reference Room of the Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

#### Regulatory Flexibility Act

4. The Commission hereby certifies pursuant to section 605(b) of the Regulatory Flexibility Act of 1990 (Pub. L. 96-354), that these rules, if promulgated, will not have a significant impact on a substantial number of small entities. Although these proposed changes allow the maritime community greater flexibility in the provision of additional forms of communications, e.g., facsimile and data, and may result in increased expenditures for equipment, such additional expenditures would be optional and would not constitute a significant economic impact on a substantial number of small business entities.

#### Paperwork Reduction

5. The proposal contained herein has been analyzed with respect to the Paperwork Reduction Act of 1980 and found to contain no new or modified form, information collection or record keeping, labeling, disclosure, or record retention requirements; and will not increase or decrease the burden hours imposed on the public.

6. Authority for issuance of the Notice of Proposed Rule Making is contained in section 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 303(r).

7. A copy of the Notice of Proposed Rule Making will be served on the Chief Counsel for Advocacy of the Small Business Administration.

#### List of Subjects in 47 CFR Part 80

Maritime stations, Coast stations, Communications equipment, Facsimile, VHF public correspondence channels.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 91-26957 Filed 11-6-91; 8:45 am]

BILLING CODE 6712-01-M

#### GENERAL SERVICES ADMINISTRATION

##### 48 CFR Parts 515 and 538

[GSAR Notice 5-330]

#### General Services Administration Acquisition Regulation; Pilot Test Under Multiple Award Schedules Program

**AGENCY:** Office of Acquisition Policy, General Services Administration (GSA).

**ACTION:** Proposed rule.

**SUMMARY:** This notice invites written comments on a proposed regulation that would temporarily amend the General Services Administration Acquisition Regulation (GSAR) to provide for test of a revised Discount Schedule and Marketing Data (DSMD) format in up to five solicitations under the Multiple Award Schedule Program and to provide for the use of a questionnaire evaluating the revised DSMD to be completed by offerors under the test.

**DATES:** Comments are due in writing on or before December 9, 1991.

**ADDRESSES:** Comments should be addressed to Bruce McConnell, GSA Desk Officer, room 3235, NEOB, Washington, DC 20503 and Marjorie Ashby, Office of GSA Acquisition Policy, 18th and F Streets, NW, room 4026, Washington DC 20405.

**FOR FURTHER INFORMATION CONTACT:** Les Davison, Office of GSA Acquisition Policy (202) 501-4768.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

Under its Multiple Award Schedule (MAS) program, GSA collects information as prescribed in the MAS Policy Statement of October 1, 1982 (47 FR 50242, November 5, 1982). The Policy Statement requires an offeror, when responding to a MAS solicitation, to provide Discount Schedule and Marketing Data (DSMD) in a specific format. The DSMD generally requires disclosure of certain pricing information on a sampling of items which have an established catalog price, and on a



items that do not have an established catalog price.

Information required to be submitted on the DSMD includes: sales to Government and non-Government customers, the highest discounts for various commercial customers, and information on an offeror's marketing practices. The DSMD is used to determine whether to grant an exemption from the statutory requirement to submit cost or pricing data based on catalog price, to establish the Government's negotiation objectives, and to determine price reasonableness. Prospective contractors that submit offers which do not qualify for the statutory exemption from submission of cost or pricing data will be requested to submit cost and pricing data in accordance with subpart 15.8 of the Federal Acquisition Regulation (FAR).

As a part of the MAS Improvement Project, GSA has drafted a restatement of its price negotiation objectives and revised the DSMD. The Government's negotiation objective will be to obtain discounts from an offeror's established catalog price which are equal to or greater than the best discounts which the offeror extends to any customer. The contracting officer may not award a contract for a discount which is less than the best discount the offeror extends to any customer (other than Federal Agencies) purchasing under circumstances comparable to the Government unless he/she makes a written determination that: (1) The prices offered to the Government are fair and reasonable, even though comparable discounts were not negotiated, and (2) award of a contract is in the best interest of the Government.

To determine whether a customer's procurement circumstances are comparable to those of the Government, the contracting officer will consider the terms and conditions of the offeror's written and/or oral agreements with customers, other than GSA, if the agreements are for the delivery, over a period of time, of items whose estimated quantity or value approximates that of the potential contract under the GSA solicitation. In analyzing such agreements, the contracting officer will consider whether any ancillary services (e.g. training, maintenance, etc.) which the offeror must perform for the non-GSA customer are similar to those it must perform under the MAS contract, and whether the terms and conditions of the non-GSA customer agreement are significantly different from those of the MAS contract.

Unless the requirement is waived, contracting officers will request cost or

pricing data in accordance with FAR subpart 15.8 and the terms of the solicitation, from offerors which do not qualify for the statutory exemption from submission of cost or pricing data. Contracting officers will evaluate all cost and/or pricing data received and negotiate a fair and reasonable price based on that evaluation and her/his price analysis.

Before awarding any MAS contract, contracting officers must determine that prices are fair and reasonable in accordance with FAR subparts 15.8 and 15.9. GSA's objectives in revising the DSMD were to ensure that (1) MAS offers submitted are accurate and complete and (2) the minimum amount of data necessary to provide GSA contracting officers sufficient information to fully evaluate MAS offers is requested. In developing the revised DSMD, GSA focused on clarifying and simplifying the data submission requirements, and on decreasing the amount of data required to be submitted by offerors.

GSA has communicated with several vendor organizations whose members are MAS contractors, invited their comments and criticisms, and fully considered their views. After considerable review and discussion of GSA's negotiation objectives and information collection requirements, a revised DSMD format has been developed. GSA believes the revised DSMD will decrease the amount of data required to be submitted by MAS offerors, while providing GSA contracting officers with adequate information to evaluate offers and negotiate fair and reasonable prices. GSA believes that a limited test usage of the revised negotiation objectives and DSMD would be prudent. Such a test would uncover unforeseen objectives and DSMD would be prudent. Such a test would uncover unforeseen problems arising from the revisions, provide for an evaluation as to whether offers received are accurate and complete and whether offerors' data disclosure requirements are actually lessened. The test would involve no more than five MAS solicitations, which are not expected to produce more than 300 offers. In addition to incorporating the revised DSMD into the solicitations, the test would include a questionnaire to be completed by offerors. The responses to the questionnaire will be used to evaluate the impact and efficacy of the revised DSMD.

#### B. Executive Order 12291

The Director, Office of Management and Budget (OMB), by memorandum dated December 14, 1984 exempted

certain agency procurement regulations from Executive Order 12291. The exemption applies to this proposed rule.

#### C. Regulatory Flexibility Act

An Initial Regulatory Flexibility Analysis has not been prepared because the proposed rule does not appear to have a significant economic impact on a substantial number of small entities, and a waiver of the requirement for both an initial and final Regulatory Flexibility Analysis is believed to be appropriate. Comments from small entities concerning the proposed rule will be considered in accordance with 5 U.S.C. 610, however.

#### D. Paperwork Reduction Act

The DSMD and the questionnaire are information collections as defined in the Paperwork Reduction Act and have been submitted to the OMB for approval under the Paperwork Reduction Act. Comments on the information collection requirements may be submitted to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Washington, DC 20503. The title of the information collection is "Pilot test of revised DSMD format used in MAS program." The DSMD require disclosure of certain pricing information on a sampling of items which have an established catalog price, and on all items that do not have an established catalog price. Information required to be submitted on the DSMD includes: sales to Government and non-Government customers, the highest discounts for various commercial customers, and information on an offeror's marketing practices. Under the MAS program, offerors responding to a MAS solicitation are requested to provide DSMD in a specific format. The DSMD is used to determine whether to grant an exemption for cost or pricing data based on catalog price, to establish the Government's negotiation objectives, and to determine price reasonableness. GSA believes that a limited test usage of the revised DSMD would be prudent. Such a test would uncover unforeseen problems arising from use of the revised DSMD, provide for an evaluation as to whether offers received are accurate and complete and whether offerors' data disclosure requirements are actually lessened. The test would involve no more than five MAS solicitations, which are not expected to produce more than 300 offers. In addition to incorporating the revised DSMD into the solicitations, the test would include a questionnaire to be completed by offerors. The responses to the questionnaire will be used to evaluate the impact and efficacy of the



revised DSMD. The estimated annual burden for the DSMD is 3,900 hours. This is based on an estimated average burden per response of 13 hours, a frequency of one response per respondent, and an estimated number of likely respondents of 300. The estimated annual burden for the questionnaire is 600 hours. This is based on an estimated average burden per response of 2 hours, a frequency of one response per respondent, and an estimated number of likely respondents of 300.

#### List of Subjects in 48 CFR Parts 515 and 538

Government procurement.

Accordingly, it is proposed to amend 48 CFR parts 515 and 538 as follows:

1. The authority citation for 48 CFR parts 515 and 538 continues to read as follows:

Authority: 40 U.S.C. 486(c).

2. 48 CFR parts 515 and 538 would be amended by the following Acquisition Circular:

#### General Services Administration Acquisition Regulation Acquisition Circular (AC-91- )

To: All GSA contracting activities.

SUBJECT: Pilot test of revised Discount Schedule and Marketing Data (DSMD) format used in Multiple Award Schedule (MAS) Program

1. *Purpose.* This Acquisition Circular temporarily amends the General Services Administration Acquisition Regulation (GSAR) chapter 5, (APS 2800.12A) to provide for pilot testing of a revised Discount Schedule and Marketing Data (DSMD) format in up to five solicitations under the Multiple Award Schedule Program and to provide for the use of a questionnaire evaluating the revised DSMD to be completed by offerors under the test.

#### 2. Background.

a. Under the MAS program, GSA collects information as prescribed in the Multiple Award Schedule Policy Statement of October 1, 1982 (47 FR 50242, November 5, 1982). The policy statement requires an offeror, when responding to a MAS solicitation, to provide DSMD in a specific format. The DSMD require disclosure of certain pricing information on a sampling of items which have an established catalog price, and on all items that do not have an established catalog price. The DSMD is used by the contracting officer to determine whether to grant an exemption for cost or pricing data based on catalog price, to establish the Government's negotiation objective, and to determine price reasonableness.

b. As a part of the MAS Improvement Project, GSA has drafted a restatement of its price negotiation objectives and revised the DSMD. The government's negotiation objective will be to obtain discounts from an offeror's established catalog or market price which are equal to or greater than the best discount which the offeror extends to any customer. The contracting officer may not award a contract for a discount which is less

than the best discount the offeror extends to any non-federal customer purchasing under circumstances comparable to the Government unless he/she makes a written determination that: (1) The prices offered to the Government are fair and reasonable, even though comparable discounts were not negotiated, and (2) award of a contract is in the best interest of the Government.

c. To determine whether a customer's procurement circumstances are comparable to those of the Government, the contracting officer will consider the terms and conditions of the offeror's written and/or oral agreements with customers, other than GSA, which agreements are for the delivery, over a period of time, of items whose estimated quantity/value approximates that of the potential contract under the GSA solicitation. In analyzing the agreements, the contracting officer will consider whether the ancillary services (e.g. training, maintenance, etc.) which the offeror must perform for the non-GSA customer are similar to those it must perform under the MAS contract, and whether the terms and conditions of the non-GSA customer agreement are significantly different from those of the MAS contract.

d. Unless the requirement is waived, contracting officers will request cost or pricing data in accordance with FAR Subpart 15.8 and the terms of the solicitation, from offerors which do not qualify for the statutory exemption from submission of cost or pricing data. Contracting officers will evaluate all cost and/or pricing data received and negotiate a fair and reasonable price based on that evaluation and her/his price analysis.

e. Before awarding any MAS contract, the contracting officer must determine that prices are fair and reasonable in accordance with FAR Subparts 15.8 and 15.9.

f. The objective in revising the DSMD was to ensure MAS offers received are accurate and complete and that offerors are required to submit the minimum amount of data necessary to provide contracting officers sufficient information to fully evaluate MAS offers. In developing the revised DSMD, GSA focused on clarifying and simplifying the data submission requirements, and on decreasing the amount of data required from offerors. Before deciding whether to adopt the revised DSMD for use under the MAS program, GSA is conducting a pilot test which involves actually using the revised DSMD in up to five solicitations to be designated by the MAS Program Coordinator.

3. *Effective date.* [To be established after consideration of public comments.]

4. *Expiration date.* [To be established after consideration of public comments. The expiration date will be one year after the effective date.]

5. *Reference to regulation.* 48 CFR chapter 5.

6. *Explanation of changes.*

a. Section 515.804-3 is amended to add paragraph (c) to read as follows:

*515.804-3 Exemption from or waiver of submission of certified cost or pricing data*

(c) The Discount Schedule and Marketing Data (DSMD) format at

GSAR 515.804-70 shall be used in lieu of the Standard Form 1412, Claim for Exemption from Submission of Certified Cost or Pricing Data, in Multiple Award Schedule solicitations identified by the GSA MAS Program Coordinator for inclusion in the pilot test of the revised DSMD. Each solicitation will require DSMDs be completed for each special item number in the solicitation and be submitted as a part of the offeror's proposal.

b. Section 515.804-70 is added to read as follows:

#### *515.804-70 Format for Discount Schedule and Marketing Data (DSMD)*

(a) As prescribed in GSAR 515.804-3(c), the contracting officer shall insert the following format for collecting the Discount Schedule and Marketing Data and the Guide for Submission of Discount Schedule and Marketing Data at Table 515-70 below, in MAS solicitations identified by the GSA MAS Program Coordinator for inclusion in the pilot test of the revised DSMD format:

#### DISCOUNT SCHEDULE AND MARKETING DATA FORMAT

Instructions necessary to complete the Discount Schedule and Marketing Data format are contained in Table 515-70 Guide For Submission of Discount Schedule and Marketing Data (DSMD) of the General Services Administration Acquisition Regulation (GSAR) and included in this solicitation for your convenience.

The Government will treat all information which the offeror submits on the DSMD as proprietary.

The Government may reject your offer if you fail to disclose accurate, complete and current data in the DSMD. If the Government discovers subsequent to contract award that information in the DSMD was not accurate, complete or current, the Government may seek refunds and other relief pursuant to the defective pricing provisions of the contract.

#### Contents

##### Part A. Offer to the Government

Part A, Sections I and II, ask for specific information about the terms of your offer to the Government.

##### Part B. Discount and Marketing Practices

Part B, Sections I and II, ask for information about the offeror's discount and marketing practices to all customer (other than Federal agencies) acquiring the same products or services offered under this solicitation.

##### Part C. Sales Information

Part C, Sections I through III, ask for information about the offeror's sales volume to Government and non-Government customers, respectively.

##### Part D. Certification

Part D requires the offeror to certify to the accuracy, currency and completeness of information submitted in Parts A-C.

Name of Offeror \_\_\_\_\_

SIN \_\_\_\_\_







exemption from the requirement to submit cost or pricing data. Items which have an "established catalog price," as defined by FAR 15.804-3 (c) and (f), will be exempted from the requirement to submit cost or pricing data. Items which meet the FAR definition are regarded as commercial items.

Sales information is given for the period \_\_\_\_\_ through \_\_\_\_\_, inclusive (Insert dates).

#### Section I—Sales Information (Total Sin)

1. TOTAL SALES TO THE U.S. GOVERNMENT FOR ALL MODELS/TYPES OR CATALOG NUMBERS OFFERED UNDER THIS SIN WERE \$\_\_\_\_\_.

2. TOTAL SALES TO ALL ENTITIES (INCLUDING THE GOVERNMENT) WITH WHOM YOU DID BUSINESS FOR ALL MODELS/TYPES OR CATALOG NUMBERS OFFERED UNDER THIS SIN WERE: \$\_\_\_\_\_.

3. LINE 1 IS \_\_\_\_\_ PERCENT (%) OR LINE 2.

4. LIST BELOW ALL MODELS/TYPES OR CATALOG NUMBERS OFFERED UNDER THIS SIN WHICH DO NOT HAVE AN "ESTABLISHED CATALOG PRICE" AS DEFINED BY FAR 15.804-3 (c) and (f), and

which do have total sales to the U.S. Government of \$25,000 or more:

5. LIST BELOW THE [contracting officer fill in the blank] MODELS/TYPES OR CATALOG NUMBERS OFFERED UNDER THIS SIN WITH THE LARGEST DOLLAR VOLUME SALES TO THE U.S. GOVERNMENT. Do not include any models listed in response to question 4, above.

6. COMPLETE THE CHART BELOW FOR EACH MODEL LISTED IN QUESTION 5:

Column O—Model type or Catalog Number

Column A—Total Sales to the U.S. Government

Column B—Total Sales to non-Government customers at catalog

price (minus any published discounts)

Column C—Total Sales to non-Government customers at other than catalog price

Column D—Total Sales (D=A+B+C)

Column E—Percentage of sales to non-Government customers at other than catalog price (minus any published discounts).

$$E = \frac{C}{(B+C)}$$

Column F—Percentage of total sales to the U.S. Government.

$$F = \frac{A}{D}$$

#### SALES INFORMATION (COMMERCIAL ITEMS)

Column O model #	Column A U.S. gov't sales	Column B non-gov't sales (catalog)	Column C non-gov't sales (other than catalog)	Column D total sales	Column E % other than catalog sales	Column F % gov't sales
(1).....						
(2).....						
(3).....						
(4).....						
(5).....						
(6).....						
(7).....						
(8).....						
(9).....						
(10).....						

7. Current MAS contractors—Total Sales under your current GSA contract for this schedule for all models/types or catalog numbers offered under this SIN were \$\_\_\_\_\_.

#### Part D—Certification

The offeror certifies that, to the best of its knowledge and belief:

(1) All of the data (including sales data submitted with this offer) are accurate, complete, and current representations of actual transactions, either (mark one):

\_\_\_\_\_ as of the date of submission of the offer;

\_\_\_\_\_ as of the date when negotiations are concluded.

(2) Substantial quantities of all items offered have been sold to the general public.

(3) Except for models identified in Part C, Paragraph 4, the price(s) quoted in this offer is (are) based on "established catalog prices" [as defined in FAR 15-804-3(c)] of commercial items sold in substantial quantities to the general public.

NAME AND TITLE OF PERSON AUTHORIZED TO SIGN ON BEHALF OF THE OFFEROR. (Type or Print).

NAME: \_\_\_\_\_

TITLE: \_\_\_\_\_

SIGNATURE: \_\_\_\_\_

OFFEROR: \_\_\_\_\_

DATE OF EXECUTION: \_\_\_\_\_

(End of format)

(b) Contract pricing proposals for MAS solicitations submitted on DSMD format in paragraph (a) above must be prepared in accordance with the instructions in Table 515-70.

#### Table 515-70 Guide for Submission of Discount Schedule and Marketing Data

This Guide contains instructions and information needed to complete and submit the Discount Schedule and Marketing Data (DSMD) portion of multiple award schedule (MAS) solicitations.

#### I. Explanations

Terms included in this section have the meanings set forth below when used in the DSMD. The explanations are in addition to any definitions and or guidance contained in the Federal Acquisition Regulation (FAR) or General Services Administration Acquisition Regulation (GSAR).

1. CUSTOMER. A "customer" is any entity, except the Federal Government, which acquires goods or services from the offeror.

The term customer includes but is not limited to, original equipment manufacturers, value added resellers, state and local governments, distributors, educational institutions, dealers, and national accounts. In any instance where the offeror is asked to disclose information for a "customer", you may disclose information by category of customer, if the offeror's discount policies are the same for all customers in the category. Disclosure of a range of discounts for customer categories is acceptable.

2. CONCESSION. A "concession" is a benefit, enhancement or privilege (other than a discount) which either reduces the overall cost of a customer's acquisition or encourages a customer to consummate a purchase. Concessions include, but are not limited to, free training, free installation, and bonus goods.

3. DISCOUNT. A "discount" is a reduction to catalog or market prices (published or unpublished) applicable to any customer. Discounts include, but are not limited to, rebates, quantity discounts, purchase option credits, trade-in-allowances, and any other terms or conditions which reduce the amount of money a customer ultimately pays for



goods or services ordered or received. Best Discounts—If your best price is a combination of discounts, identify each type of discount used. (For example, 1 to 99—20% regular discount; 100+ —25% quantity discount; 2% aggregate discount on sales exceeding \$50,000).

4. **EDUCATIONAL INSTITUTION.** An "educational institution" is an elementary, junior high, or degree granting school which maintains a regular faculty, an established curriculum and an organized body of students. Offerors shall disclose discounts given to educational institutions when required by PART C. Discounts to educational institutions will not serve as a negotiation objective unless the offeror has no other significant category of customer. The Government will, however, negotiate for such discounts for use by comparable Federal educational institutions. Examples of Federal educational institutions include: the service academies, Department of Defense dependent schools, Bureau of Indian Affairs Schools.

5. **ITEM.** An "item" is a product or service which is separately priced and offered to a customer for sale, lease or rental.

6. **U.S. GOVERNMENT SALES.** U.S. Government sales include all Government sales, regardless of whether the orders were placed against a GSA Schedule contract.

## II. General Instructions

1. The DSMD is composed of four Parts, A through D, which solicit information about the offeror's discount and marketing practices and its offer to the Government.

2. Complete Parts A through C for each Special Item Number (SIN) included in your offer. Respond to each question. You may make a single submission of each Part, covering more than one SIN, if the information disclosed is the same for all products under each SIN. Complete Part D once for the entire offer.

3. The Government will use information which the offeror discloses to establish negotiation goals, determine if the prices offered are reasonable, and determine whether the items offered qualify for an exemption from the FAR requirement to submit cost or pricing data.

4. If an offeror does not disclose accurate, complete and current data, the Government may reject the offer or, if a contract has been awarded, seek refunds and other relief pursuant to the defective pricing clause in the MAS solicitation.

5. The Government will treat all information which the offeror submits on the DSMD as proprietary. The information will be withheld from disclosure in accordance with section 27 of the Office of Federal Procurement Policy Act, as amended (41 U.S.C. 423) and the Freedom of Information Act. The identity of items actually awarded and contract prices, however, are public information which will be disclosed by the Government.

6. Offerors may reproduce the DSMD as necessary. If any section of the DSMD does not provide adequate space for a complete answer, the offeror may continue its response by attaching pages.

7. Contracting officers may request documentation in addition to that specified

on the DSMD's if such documentation is necessary to determine that discounts, terms and conditions, offered the Government are fair and reasonable.

## III. Instructions for Completing Part A

Section I asks for general information about the offer. Section II asks for information concerning discounts which you offer the Government.

1. If you do not offer a discount specified in PART A, enter zero.

2. You may offer discounts and concessions which vary by model or product line. If you offer varying discounts, you must either: (i) annotate the price list to show discounts applicable to each model or product line, or (ii) complete a supplemental sheet in the format shown at the end of this Guide.

## IV. Instructions for Completing Part B

1. If the offeror's discount practices vary by model or product line, give discount information by model or product line.

2. Disclose discounts and discounting practices which are in effect up to the close of negotiations.

3. Disclose discounts to current customers without regard to the terms and conditions of the agreements under which the discounts are offered, and without regard to whether such agreements are written or verbal.

4. If the prices offered any customer are not (i) a discount from the price list which is the basis for your offer to GSA, or (ii) a discount from a price list, you should convert the low price into a discount from the price list which is the proposed basis for your agreement with GSA.

## V. Instructions for Completing Part C

1. Complete a separate PART C for each Special Item Number (SIN) for which you submit an offer.

2. Complete the chart entitled "Sales Information (Commercial)" for each model listed in response to question 5.

3. Applicable to questions 1 through 6. Submit all requested sales information for a consecutive 12 month period. The offeror may choose any 12 month period for which it has reliable sales information, provided that the period may not begin prior to the beginning of your most recently completed fiscal or tax year.

## VI. Instructions for Completing Part D

Offerors must certify, at the time their initial proposals are submitted that sales, discount and marketing data included with those proposals is current as of the date the proposal is submitted. At the conclusion of negotiations, offerors must certify that any additional information provided to the Government during the negotiation process is accurate, complete and current.

## SUPPLEMENTAL SHEET

(Ref. Guide III, 2, ii)

Column 1 Model #	Column 2 Discount from pricelist	Column 3 Price list and date

(END OF GUIDE)

c. Section 538.203-70 is added to read as follows:

## 538.203-70 Submission of discount schedule and marketing data.

The contracting officer shall insert the Discount Schedule and Marketing Data (DSMD) format at GSAR 515.804-70 in multiple award schedule (MAS) solicitations identified by the GSA MAS Program Coordinator for inclusion in the test of the revised DSMD format.

7. **Questionnaire.** The Questionnaire for the Revised DSMD Test Evaluation is illustrated as an attachment to this Circular. Offerors responding to MAS solicitations under the test program will be asked to complete the questionnaire and return it after MAS contracts resulting from the solicitations are awarded.

Dated: October 30, 1991.

Richard H. Hopf III,  
Associate Administrator for Acquisition Policy

(Note: This attachment will not appear in the Code of Federal Regulations)

## Attachment to AC-91-Questionnaire for Revised DSMD Test Evaluation

Schedule \_\_\_\_\_  
Product \_\_\_\_\_  
Solicitation Number \_\_\_\_\_  
Contractor Name (Optional) \_\_\_\_\_  
Small Business \_\_\_\_\_  
Large Business \_\_\_\_\_  
Number of Items offered by your firm \_\_\_\_\_  
Number of SIN's offered by your firm \_\_\_\_\_

1. Is this the first time you have submitted an offer on a GSA Multiple Award Schedule Program? Yes \_\_\_\_\_ No \_\_\_\_\_

If "no" how many times (approx) have you submitted Discount Schedule & Marketing Data (DSMD) to GSA prior to this solicitation? \_\_\_\_\_

2. Did your offer on this solicitation result in the award of a contract to your firm? Yes \_\_\_\_\_ No \_\_\_\_\_  
If "no" why not? \_\_\_\_\_

3. Do you expect to submit offers on future GSA Multiple Award Schedule solicitations, for this Schedule or any other? Yes \_\_\_\_\_ No \_\_\_\_\_  
If "no" please explain. \_\_\_\_\_

4. Based on my experience preparing the offer for this solicitation and negotiating the terms of the offer, I found the revised DSMD to be:

	Yes	No
Clear	_____	_____
Confusing	_____	_____
Concise	_____	_____
Too lengthy	_____	_____
Too brief	_____	_____



	Yes	No
Logical.....	___	___
Too inflexible.....	___	___
Appropriate.....	___	___

Please explain in detail. (Attach additional sheets as necessary.) \_\_\_\_\_

5. The new "Guide for Submission of Discount Schedule and Marketing Data" was included with the revised DSMD. I found the Guide to be:

	Yes	No
Very helpful.....	___	___
Helpful.....	___	___
Not helpful.....	___	___
Clear.....	___	___
Concise.....	___	___
Confusing.....	___	___

Please explain. \_\_\_\_\_

6. These questions compare the revised DSMD and the old DSMD. If you have not previously submitted "old" DSMD, indicate "N/A." Which one:

	Revised	Old	No. Diff.
(a) Had more easily understandable instructions.	___	___	___
(b) Required more time to gather and submit necessary information.	___	___	___
(c) Required more information to be submitted.	___	___	___
(1) with your original offer.	___	___	___
(2) during the evaluation/negotiation process.	___	___	___

	Revised	Old	No. Diff.
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(d) Resulted in your lowest priced initial offer to GSA.

(e) Resulted in the quickest negotiation agreement.

7. The revised DSMD are intended to solicit sufficient information to allow the Contracting Officer to evaluate and negotiate fair and reasonable prices for GSA. Are the data submission requirements of the revised DSMD consistent with that purpose? \_\_\_ Yes \_\_\_ No \_\_\_ Don't know  
If "no," do the revised DSMD require submission of: \_\_\_ a) too much data; \_\_\_ b) too little data  
What should be changed? \_\_\_\_\_

8. Were you requested to submit additional information, after the initial submission of your offer? \_\_\_ Yes \_\_\_ No  
If "yes," what type of additional information was requested? \_\_\_\_\_

9. a) Did you offer the Government your best discount in your initial offer? \_\_\_ Yes \_\_\_ No

b) If you were awarded a contract, does the Government receive equal to or better than your best discount? \_\_\_ Yes \_\_\_ No

10. Please highlight, from your experience, the strengths and weaknesses of the revised DSMD? (Please be as specific as possible.) \_\_\_\_\_

11. Which do you prefer? \_\_\_ Old DSMD \_\_\_ Revised DSMD \_\_\_ No preference  
Please explain. \_\_\_\_\_

12. Do you recommend using the revised DSMD in other GSA multiple award schedule solicitations? \_\_\_ Yes \_\_\_ No \_\_\_ No opinion  
Please explain. \_\_\_\_\_

13. Do you think the revised DSMD represent an improvement? \_\_\_ Yes \_\_\_ No \_\_\_ No opinion  
Please explain. \_\_\_\_\_

14. Please provide any other comments on the revised DSMD you would like to share? \_\_\_\_\_

15. Please estimate the total number of hours expended (for all persons) to complete the DSMD portion of this offer for a single Special Item Number (SIN). \_\_\_ hours

16. If your firm had previously submitted an offer to GSA using the old DSMD: Which DSMD required more effort? \_\_\_ Old \_\_\_ Revised

Approximately how much more? \_\_\_ hours per SIN

Please indicate specific areas that required significantly more or less time. \_\_\_\_\_

[FR Doc. 91-26725 Filed 11-6-91; 8:45 am]

BILLING CODE 6820-61-M

## DEPARTMENT OF TRANSPORTATION

### Research and Special Programs Administration

#### 49 CFR Parts 107 and 171

[Docket No. HM-208, Notice No. 91-4]

RIN 2137-AB43

### Hazardous Materials Transportation Registration and Fee Assessment Program; Additional Hearing Date

**AGENCY:** Research and Special Programs Administration (RSPA), DOT.

**ACTION:** Proposed rule; announcement of an additional hearing.

**SUMMARY:** On October 10, 1991, a Notice of Proposed Rulemaking was published in the *Federal Register* [56 FR 51294] proposing to establish a national registration and fee assessment program for certain shippers and carriers of hazardous materials and certain hazardous materials package manufacturers. Interested persons were invited to submit comments on the proposal and public hearings were announced for October 21, 1991, in Burlingame, California and October 31, 1991, in Des Plaines, Illinois. Because of considerable interest in the proposed registration and fee assessment program, RSPA is scheduling an additional hearing to be held in Washington, DC on November 26, 1991 from 9:30 a.m. to 5 p.m.

**DATES:** The date of the hearing is November 26, 1991, from 9:30 a.m. to 5 p.m. The hearing may close earlier than 5 p.m. upon presentation of oral comments from all persons desiring to comment.

**ADDRESSES:** The hearing will be held in room 2230 of the Nassif Building, U.S.



Department of Transportation, 400 Seventh Street SW., Washington, DC 20590-0001.

**FOR FURTHER INFORMATION CONTACT:**

Beth Romo, Office of Hazardous Materials Standards, (202) 366-4488, Hazardous Materials Safety, Research and Special Programs Administration, 400 Seventh Street SW., Washington, DC 20590-0001.

**SUPPLEMENTARY INFORMATION:** Any person wishing to present an oral statement at the public hearing should notify the Office of Hazardous Materials Standards, by telephone or in writing, at least two days in advance of the hearing date. Each request must identify the speaker; organization represented, if any; daytime telephone number; and the anticipated length of the presentation, not to exceed ten minutes. Written text of oral statements should be presented to the hearing officer prior to the oral presentation.

Issued in Washington, DC on November 1, 1991, under the authority delegated in 49 CFR part 1.

Alan I. Roberts,

Associate Administrator for Hazardous Materials Safety.

[FR Doc. 91-26856 Filed 11-6-91; 8:45 am]

BILLING CODE 4910-60-M

**National Highway Traffic Safety Administration**

**49 CFR Part 582**

[Docket No. 74-40; Notice 3]

RIN 2127-AE18

**Insurance Cost Information Regulation**

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to amend part 582, Insurance Cost Information Regulation, to require automobile dealers to make available insurance collision loss experience information compiled by the Highway Loss Data Institute (HLDI) to prospective purchasers of passenger vehicles. The amendment would implement section 201(e) of the Motor Vehicle Information and Cost Savings Act. This notice also sets forth a sample form for presentation of the HLDI information. These proposed amendments would assist prospective purchasers in comparing differences in collision loss experience for different passenger vehicles that could affect auto insurance costs.

**DATES:** Comments on this proposal must be received by NHTSA no later than

December 23, 1991. If adopted in a final rule, these amendments would take effect 30 days after publication of the final rule in the Federal Register.

**ADDRESSES:** Comments should refer to Docket No. 74-40; Notice 3, and be submitted to: Docket Section, room 5109, NHTSA, 400 Seventh Street, SW., Washington, DC 20590. (202) 366-5267. The docket section is open from 9:30 a.m. to 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Mr. Nelson G. Gordy, Office of Market Incentives, NHTSA, 400 Seventh Street SW., Washington, DC 20590 (202-366-4797).

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 201(e) of title II of the Motor Vehicle Information and Cost Savings Act ("Act"), 15 U.S.C. 1941(e), states:

The Secretary (of Transportation), not later than February 1, 1975, shall by rule establish procedures requiring automobile dealers to distribute to prospective purchasers information developed by the Secretary and provided to the dealer which compares differences in insurance costs for different makes and models of passenger motor vehicles based upon differences in damage susceptibility and crashworthiness.

On January 31, 1975, NHTSA issued 49 CFR part 582, Insurance Cost Information Regulation (40 FR 4918). Part 582 requires that automobile dealers "make available to prospective purchasers information reflecting differences in insurance costs for different makes and models of passenger motor vehicles based upon differences in damage susceptibility and crashworthiness." However, the regulation left to a subsequent rulemaking proceeding the specification of the particular information to be made available and the form in which it is to appear. This proposal marks the beginning of that proceeding. It would complement the 1975 final rule and complete the implementation of part 582.

**Agency Studies**

From June 1974 through January 1976, NHTSA conducted studies on damage susceptibility and crashworthiness characteristics of passenger vehicles. Among other things, the studies sought to determine the effect that these factors have upon insurance premiums. The agency concluded that:

(C)urrent rates are not influenced to any great degree by vehicle damage susceptibility or safety characteristics. Although it is economically logical that a degree of cost savings (premium reduction) could be applied to those vehicles having superior characteristics, the current premium structure would minimize the effect of those vehicle

characteristics since it is primarily influenced by driver and geographical factors, in addition to the price of the car [Ref. Report DOT HS-801 844].

The premium structure remains essentially unchanged in today's insurance market, except that some insurance companies have added discounts for vehicles equipped with either automatic restraints, anti-lock braking systems or both.

**Consumer Information Programs**

Following the insurance premium studies, the agency embarked on two consumer information programs to fulfill other requirements of section 201 of the Act. These requirements include:

(a) \* \* \* [A] comprehensive study and investigation of the methods for determining the following characteristics of passenger motor vehicles: (1) The damage susceptibility of such vehicles. (2) The degree of crashworthiness of such vehicles \* \* \*.

(c) After the study has been completed the Secretary is authorized and directed to devise specific ways in which \* \* \* information \* \* \* can be communicated to consumers so as to be of benefit in their passenger motor vehicle purchasing decisions.

The agency initiated two programs to communicate appropriate information to consumers. The first was a bumper rating program to determine the relative damage susceptibility of vehicle bumper systems in low-speed front and rear collisions (47 FR 21819; May 20, 1982). The second was a high-speed frontal crash test program to evaluate the relative protection from personal injury which the vehicle provides to its occupants (i.e., crashworthiness). These two programs also had the potential to generate information regarding factors that might influence insurance premiums and thus to indicate the extent to which differences in insurance costs may be based on differences in damage susceptibility and crashworthiness between different makes and models of automobiles.

The bumper rating program was terminated because a correlation between low-speed bumper impact tests and real-world accident experience was not achievable. In 1985, the agency concluded that data sources for low speed accident incidence and repair costs did not exist, and that such data could not be developed.

In contrast, the high speed frontal crash program was a success. Using data from that program, the agency established the New Car Assessment Program (NCAP). NCAP provides comparative crashworthiness data to guide consumers in making their vehicle



purchasing decisions and in encouraging manufacturers to improve the safety characteristics of their passenger vehicles.

However, these comparative crashworthiness data have not been used extensively by the insurance companies to adjust their premiums for at least two reasons. First, while NCAP data are for restrained test dummies, many occupants involved in injury-producing crashes have traditionally not used the vehicle's restraint systems. Second, the portion of insurance premiums related to vehicle crashworthiness (i.e., medical and personal injury coverage) usually constitutes only about 10 percent of the total insurance premium costs. Therefore, any adjustments to insurance premiums based on the NCAP data would have minimal effects on the total amount paid by vehicle owners for premiums.

As a general rule, medical and personal injury premiums are not affected by a vehicle's safety features, except for discounts which many insurance companies are not offering for vehicles with airbags and/or anti-lock brake systems. For example, one insurance company offers a 20 percent discount on medical and personal injury premiums for a vehicle equipped with a driver-side-only airbag and a 30 percent discount for a vehicle equipped with both driver-side and passenger-side air bags. The annual discounts in this case would amount to \$22.00 for a driver-side airbag and \$34.00 for a full front airbag system. This reduction is small compared to a typical total premium of \$900.00 per year.

#### Bumper Standard

In addition to these programs, NHTSA issued a bumper standard as required by title I of the Act. Section 102 of the Act specifies:

(T)he Secretary by rule (1) shall promulgate bumper standards applicable to all passenger motor vehicles manufactured or imported into the United States \* \* \*. Any standard \* \* \* shall seek to obtain the maximum feasible reduction of costs to the public and to the consumer.

On March 4, 1976, NHTSA issued a final rule which required that bumpers on passenger cars sustain no damage (except to facebars and facebar fasteners) in impacts into a fixed barrier at speeds up to 5 mph (41 FR 9346). On May 20, 1982, after extensive analysis of the costs and benefits of 5 mph bumpers, the standard was amended to require 2.5 mph bumpers instead of 5 mph bumpers (47 FR 21820). On petition for review, this amendment was affirmed by the United States Court of Appeals for the

District of Columbia Circuit. *Center for Auto Safety v. Peck*, 751 F.2d 1336 (DC Cir. 1985).

#### CU Petition and Lawsuit

On April 7, 1986, Consumers Union of United States (CU) petitioned NHTSA to restore the 5 mph bumper standard or, in the alternative, to require automobile dealers to disclose information relating to the performance of passenger cars in 5 mph collisions. This information would have consisted of a numerical ranking for each passenger car model, estimates of the repair cost for damage in the 5 mph tests, and insurance renewal premium surcharges related to these repair costs. In addition, CU stated that if the agency denied those requests, it should take action to require automobile dealers to distribute information about repair costs and the insurance renewal surcharges related to those repair costs.

The agency denied CU's petition in a notice published on June 15, 1990 (55 FR 24264). NHTSA based its denial of the first request primarily on the results of its extensive 1987 study of the benefits and costs to consumers of an amended bumper standard. The study indicated that the reduced protection of 2.5 mph bumpers, compared to the level of protection provided by 5 mph bumpers, would lead to more vehicle damage in low-speed crashes. However, the agency found that this increase would be more than offset by consumer savings in the original and the replacement costs of the 2.5 mph bumpers and in fuel savings due to those bumpers' lighter weight.

NHTSA also denied CU's alternative requests. The agency could not find consistent positive correlation between damage induced in laboratory bumper tests and insurance accident repair costs. The agency also noted that insurance premium rates did not appear to be influenced significantly by vehicle damage susceptibility. In particular, data available to the agency indicated that specific components that might affect such susceptibility, such as bumpers, did not significantly affect the premium costs of auto insurance.

Accordingly, the agency stated that requiring new car dealers to make available the information specified in the petitioner's alternative requests would not provide prospective purchasers of passenger vehicles with useful information.

In September 1990, CU filed suit against the Secretary of the Department of Transportation and the Administrator of NHTSA to compel the agency to "develop and ensure disclosure of comparative insurance cost information" in accordance with section 201(e). *Consumers Union v. Skinner*, No.

90-2369 (D.D.C., filed September 26, 1990).

#### Proposed Insurance Cost Information Program

In response to the lawsuit, agency officials met with representatives of CU and the Insurance Institute for Highway Safety (IIHS) and further scrutinized insurance data in an effort to determine if there is a correlation between insurance premiums and vehicle crashworthiness and/or damage susceptibility. Based on this review, the agency continues to believe that there is no direct relationship between crashworthiness and insurance premiums and that vehicle damage susceptibility has a relatively minor impact on insurance premium rates. Nevertheless, the agency has tentatively determined that the collision insurance portion of automobile insurance premiums is related to some degree to a vehicle's real-world collision loss experience. Following an inquiry into methods used by insurance companies to set premiums for collision coverage, NHTSA has tentatively concluded that collision loss experience data collected and reported by the Highway Loss Data Institute (HLDI) is the best available indicator of the effect of damage susceptibility on insurance costs.

HLDI gathers, processes, and provides the public with data on human and economic losses resulting from automobile crashes. HLDI publishes statistical information regarding the number and extent of collision or vehicle damage losses associated with most passenger motor vehicles, based on a detailed annual statistical report, HLDI R 89-2.

HLDI's statistics are based on insurance claim and coverage data furnished by Aetna Life and Casualty Co., Allstate Insurance Co., Fireman's Fund Insurance Co., Government Employees Insurance Company (GEICO), Kemper Corp., Liberty Mutual Insurance Co., Nationwide Mutual Insurance Co., The Prudential Insurance Co., Safeco Corp., Sentry Insurance Mutual Company, State Farm Mutual Automobile Insurance Co., The Travelers Corp., and United Services Automobile Association (USAA). These data, representing the combined experience of those insurance companies that write approximately 45 percent of all automobile insurance policies, is large enough to provide detailed and statistically significant information about most passenger motor vehicles. This information, updated on an annual basis, is published by HLDI in September of each year in a pamphlet



entitled "Injury and Collision Loss Experience by Make and Model." It reflects the collision loss experience of vehicle makes and models and from two earlier model years (i.e., the September 1990 HLDI pamphlet includes collision information from 1988 and 1989 model year vehicles.)

Three kinds of statistics concerning collision losses are reported by HLDI. The first, "claim frequency," provides a count of insurance claims in relation to the number of vehicles insured. The second, "claim cost," indicates the average loss payment per claim. The third statistic, "average loss payment per insured vehicle year," combines the first two statistics to indicate the average loss payment per vehicle per year. The average loss payment per insured vehicle year is reported in relative terms, with 100 representing the average for all vehicles. Thus, a vehicle with a rating of 122 has had a collision loss experience that is 22 percent higher (worse) than average while a vehicle with a rating of 96 has had a collision loss experience that is four percent lower (better) than average.

In general, HLDI has found that passenger vehicles with the best collision loss experience are large models, while those with the worst experience are small cars. Notwithstanding this general finding, differences among cars of the same size and body style may be considerable. For example, in the 1990 pamphlet, among midsize, four-door models, one model had a relative loss payment per insured vehicle year of 51, much better than the average. On the other hand, the worst model in the same group had a relative loss payment rating of 123.

Usually, the patterns reflected in this data tend to be relatively stable from one model year to another. However, if manufacturers change the design of their vehicles, collision loss results could change. In such cases, the results for the earlier models will not accurately predict the loss experience (or the insurance premium) of the new or redesigned models. The agency notes that HLDI would determine when there has been such a design change and that organization's pamphlet does not include models with dramatic changes. In addition, some models are not included in the HLDI report because there are insufficient data to compute collision loss results that are statistically meaningful.

Most insurance companies use the information collected by HLDI to adjust their premiums for collision coverage. Typically, each make and model is assigned a base rate according to the manufacturer's suggested retail price or,

for older cars, their appraised value. The companies then adjust this base rate upward if the loss experience of the particular model is worse than average, or downward if it is better than average. For example, if a particular model has a relative average loss payment of 115 (15 percent worse than average for all cars), its base rate for collision coverage may be adjusted upward by approximately 15 percent. Adjustments for new models that do not have a collision loss history may be based on the experience of similar models from previous years. Generally, new models with no comparable prior year models are rated initially according to their price, with adjustments made in future years, as relevant claims data become available.

There are several important limitations on the ability of the HLDI data to reflect differences in insurance costs due to damage susceptibility. The information is only applicable to the collision portion of the insurance premium and not to the total premium. Although collision coverage generally is not mandatory and its cost varies with the deductible amount, the average for those who opt for some collision coverage represents about 40 to 50 percent of total premium cost.

In addition, most of the factors associated with determining the cost of automobile insurance, except for the vehicle's value, are not directly related to the vehicle itself. The primary factors in determining insurance rates are driver characteristics (e.g., age, gender, marital status, driving record) and the geographic area in which the vehicle is driven. Other non-vehicle factors that affect insurance cost include amount of vehicle usage and number of vehicles owned. In addition, different insurance companies may have significantly different premiums for a given insured driver and vehicle, based on the companies' overhead and other factors. Thus, consumers will have to contact their insurance companies directly to ascertain the actual premiums that will be charged for particular vehicles.

As this discussion demonstrates, while the HLDI collision claims data do not directly provide information on differences in actual insurance costs among vehicles based on their damage susceptibility, collision loss experience is one of several factors in the determination of insurance premiums for collision coverage. Thus, the data appear to be the best available reflection of "differences in insurance costs based upon differences in damage susceptibility" that Congress directed NHTSA to require dealers to provide to consumers in section 201(e) of the Act.

Accordingly, NHTSA has tentatively decided to require that automobile dealers make the HLDI collision claims data, reflecting the relative "average loss payment per insured vehicle year," available to prospective purchasers of passenger motor vehicles. While part 582 currently applies to new and used automobile dealers, the agency has tentatively decided to limit its application to new dealers. Such a limitation would appear to be consistent with the HLDI data which concerns the collision loss experience of automobiles from the preceding three model years. In addition, only new automobile dealers are required to distribute the Environmental Protection Agency's fuel economy booklet under 40 CFR 600.401-77 (subpart E). The definition for "automobile dealer" in § 582.3(b) would be modified to reflect this change. The agency welcomes comments about whether used automobile dealers should also be required to distribute the information.

The agency is proposing to require dealers to present the information as set forth below. The form would include introductory text and tables of data. The text would explain the HLDI data and the limitations on its use. It would also advise consumers that information on vehicle crashworthiness in frontal collisions is available from NHTSA through the NCAP program.

Although the text would remain the same, the accompanying data would change each year. NHTSA intends to publish the updated data each fall in the *Federal Register* as they are reported by HLDI. Dealers would be required to make the data available to prospective purchasers within 30 days of publication in the *Federal Register*. Under this alternative, the agency anticipates that vehicle manufacturers or trade associations representing dealer interests could make these booklets available to the dealers. An alternative method of distribution could be patterned after the system used with EPA's fuel economy booklets in which the government publishes the booklets and then sends copies to each dealer. A third method would be for the government to supply a sample booklet but have the dealer responsible for making copies of that booklet. The agency welcomes comments about the most effective way to distribute this information.

As indicated on the sample, for ease of use by consumers, the agency proposes to group vehicles by type and size and to list vehicle makes and models falling within a particular group in alphabetical order. However, w



would appreciate comments on whether alternative methods of ordering vehicles would be more effective.

HLDI also provides data on personal injury loss experience by make and model of passenger vehicle. However, since Personal Injury Protection (PIP) coverage represents a very small portion of the total premium (typically ten percent or less), and is generally the same for all makes and models covered by an insurer (aside from possible discounts for vehicle safety features and possible surcharges for "high performance" vehicles), this information does not significantly affect insurance rates. Therefore, the agency has not proposed to require dealers to make this information available to prospective purchasers pursuant to part 582. The agency welcomes comments about whether HLDI information about PIP claims experience should be distributed.

#### Rulemaking Analyses and Notices

##### *Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures*

The agency has analyzed the economic and other effects of this proposal and tentatively determined that they are neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department of Transportation regulatory policies and procedures. The agency has tentatively determined that the economic effects of the proposed amendments are minimal so that a full regulatory evaluation is not required. The agency estimates that the proposed insurance cost information regulation would cost new vehicle dealers a total of less than \$500,000 per year. This estimate is based on the following considerations: The HLDI four-page color pamphlet, which contains more information than would be required in the proposal, cost between \$0.03 and \$0.04 per copy to produce (for a volume of 3 million copies); and approximately 10 million new cars are sold each year. Accordingly, a "worst-case" materials cost would be \$300,000 to \$400,000. However, since the form may be less expensive and this information will probably not be requested by all customers, the materials costs should be less than the above estimate. Shipping costs to obtain the pamphlets, assuming \$2.50 per dealership, would total \$60,000 for 24,000 new automobile dealerships. Storage costs would be insignificant and administrative costs would be incidental. Commenters are specifically asked to provide information about the cost impacts of the proposed regulation.

#### *Regulatory Flexibility Act*

In accordance with the Regulatory Flexibility Act, NHTSA has evaluated the effects of this proposed action on small entities. There are about 24,000 new automobile dealers, many of which would be considered small entities, that would be affected by this proposed regulation. However, NHTSA believes that this proposed regulation would not have a significant economic effect on these dealers. The potential cost increments associated with this proposed action should have negligible effects on the purchase price of new passenger cars, if any. Thus, small organizations and small governmental jurisdictions that purchase passenger cars should not be significantly affected. Based upon this evaluation, I certify that the proposed amendments would not have a significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysts has been prepared.

##### *Executive Order 12612 (Federalism)*

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been tentatively determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### *National Environmental Policy Act*

The agency has also analyzed this proposed rule for the purpose of the National Environmental Policy Act, and tentatively determined that it would not have any significant impact on the quality of the human environment.

#### *Procedures for Filing Comments*

It is requested but not required that 10 copies be submitted. All comments must not exceed 15 pages in length. (49 CFR 553.21). Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the

agency's confidential business information regulation. 49 CFR part 512.

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments received too late for consideration in regard to the final rule will be considered as suggestions for further rulemaking action. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

#### **List of Subjects in 49 CFR Part 582**

Insurance, Motor vehicles.

In consideration of the foregoing, NHTSA proposes to amend 49 CFR part 582 as follows:

#### **PART 582—[AMENDED]**

1. The authority citation for part 582 would continue to read as follows:

**Authority:** 15 U.S.C. 1941(e); delegation of authority at 49 CFR 1.51.

2. In § 582.3, paragraphs (b)(3) and (4) would be removed and paragraph (b)(1) would be revised to read as follows:

##### **§ 582.3 Definitions.**

\* \* \* \* \*

(b) \* \* \*

(1) *Automobile dealer* means any person who engages in the retail sale of new automobiles as a trade or business.

3. Section 582.4 would be revised to read as follows:

##### **§ 582.4 Requirements.**

(a) Each automobile dealer shall provide the information specified in § 582.5 for examination by prospective purchasers at each location where he or she offers vehicles for sale.

(b) The information shall be provided without charge and in sufficient quantity to have it available for retention by prospective purchasers, within 30 days after its publication **Federal Register**.

4. Section 582.5 would be revised to read as follows:



**§ 582.5 Information form.**

The information provided pursuant to § 582.4 shall be presented in writing in the English language and in not less than 10 point type in the format set forth in the sample form below. It shall include the explanatory text and complete data on all vehicles published annually in the Federal Register by the National Highway Traffic Safety Administration.

**Sample Form—Comparison of the Collision Loss Experience of Passenger Motor Vehicles**

In order to provide information to prospective purchasers that compares differences in insurance costs for different makes and models of passenger motor vehicles based on differences in damage susceptibility, the National Highway Traffic Safety Administration (NHTSA) has prepared the following table. The information in the table was taken from the data compiled and reported by the Highway Loss Data Institute (HLDI) in its "Injury and Collision Loss Experience," September 1990, pamphlet. It reflects the collision loss experience of passenger vehicles sold in the United States in terms of the average loss payment per insured vehicle year for 1988 and 1989 model year vehicles. The vehicles' collision loss experience is shown in relative terms, with 100 representing the average for all passenger vehicles. Thus, a vehicle with a rating of 122 has had a collision loss experience that is 22 percent higher (worse) than average while a vehicle with a rating of 96 has had a collision loss experience that is four percent lower (better) than average. New models, and models without enough claim experience, are not included in the table.

Some insurance companies use this information to adjust rates for the collision portion of their auto insurance premiums, which on average make up approximately 40 to 50 percent of the total insurance premium. However, most companies do not adjust their premiums for liability coverage, personal injury protection, or medical payments coverage on the basis of vehicle factors, except that some companies offer discounts for vehicles equipped with air bags, automatic belts, or antilock brake systems, and rates are sometimes higher for "high performance" cars.

Consumers should be aware that most of the factors associated with determining automobile insurance premiums, except for the vehicle's value, are not directly related to the vehicle itself. The primary factors in determining insurance costs are driver characteristics (e.g., age, gender, marital status, driving record) and the geographic area in which the vehicle is driven. Other non-vehicle factors which affect premiums include the amount and type of vehicle usage and the number of vehicles owned. In addition, different insurance companies may charge significantly different premiums in the same geographic area for a given insured driver and vehicle. Therefore, consumers should contact their insurance companies directly to determine the actual premium that will charge for insuring a particular vehicle.

While the crashworthiness of vehicles is generally not reflected in insurance

premiums, test data relating to vehicle crashworthiness are available from NHTSA's New Car Assessment Program (NCAP). NCAP test results demonstrate relative frontal crash protection in new vehicles. Information on vehicles that have been tested by NHTSA can be obtained by calling the agency's toll-free Auto Safety Hotline at (800) 424-9393.

**TABLE****Station Wagons and Passenger Vans**

	Collision Loss
<b>Large:</b>	
Buick Electra .....	082
Chevrolet Astro Van .....	050
Chevrolet Caprice .....	059
Dodge Caravan .....	051
Dodge Grand Caravan .....	051
Ford Extended Aerostar .....	053
Ford Aerostar .....	061
Ford Crown Victoria .....	071
GMC Safari Van .....	053
Plymouth Grand Voyager .....	050
Plymouth Voyager .....	055
Pontiac Safari Wagon .....	052
Mazda Wagon .....	087
Mercury Grand Marquis .....	082
Oldsmobile Custom Cruiser .....	058
<b>Midsized:</b>	
Buick Century .....	065
Chevrolet Cavalier .....	081
Chevrolet Celebrity .....	071
Dodge Colt Vista 4WD .....	063
Dodge Colt Vista .....	099
Ford Taurus .....	069
Mercury Sable .....	077
Oldsmobile Cutlass Ciera .....	075
Plymouth Colt Vista .....	094
Pontiac 6000 .....	083
Toyota Camry .....	067
Volvo 240 .....	086
<b>Small:</b>	
Ford Escort .....	082
Honda Civic .....	062
Honda Civic 4WD .....	071
Mazda 323 .....	081
Mitsubishi Wagon .....	111
Nissan Sentra .....	094
Subaru DL/GL .....	076
Toyota Corolla .....	088
Toyota Van .....	081
Volkswagen Fox .....	097

**Four-Door Models**

<b>Large:</b>	
Buick Electra .....	072
Buick LeSabre .....	069
Chevrolet Caprice .....	056
Ford Crown Victoria .....	064
Mercury Grand Marquis .....	071
Oldsmobile 88 .....	075
Oldsmobile 98 .....	080
Pontiac Bonneville .....	074
<b>Midsized:</b>	
Buick Century .....	069
Buick Skyhawk .....	092
Buick Skylark .....	087
Chrysler LeBaron (hatchback) .....	072
Chrysler New Yorker .....	078
Chevrolet Cavalier .....	086
Chevrolet Celebrity .....	070

**TABLE—Continued**

	Collision Loss
Chevrolet Corsica .....	089
Dodge Aries .....	072
Dodge Dynasty .....	055
Dodge Lancer .....	091
Dodge Spirit .....	051
Eagle Premier .....	071
Ford Taurus .....	081
Ford Tempo .....	078
Ford Tempo 4WD .....	076
Honda Accord .....	101
Mazda 626 .....	100
Mazda 929 .....	105
Mercury Sable .....	084
Mercury Topaz .....	079
Mitsubishi Galant .....	115
Mitsubishi Sigma .....	103
Nissan Stanza .....	099
Nissan Maxima .....	122
Oldsmobile Calais .....	090
Oldsmobile Cutlass Ciera .....	074
Plymouth Acclaim .....	052
Plymouth Reliant .....	076
Pontiac Grand Am .....	085
Pontiac Sunbird .....	093
Pontiac 6000 .....	085
Toyota Camry .....	078
Toyota Cressida .....	123
Volvo 240 .....	083
<b>Small:</b>	
Acura Integra .....	122
Chevrolet Spectrum .....	114
Chevrolet Sprint .....	107
Dodge Shadow .....	090
Dodge Omni .....	089
Ford Escort .....	103
Honda Civic .....	102
Hyundai Excel .....	112
Isuzu I-Mark .....	103
Mazda 323 .....	103
Mercury Tracer .....	108
Nissan Sentra .....	122
Plymouth Horizon .....	080
Plymouth Sundance .....	096
Saab 900 .....	154
Pontiac LeMans .....	127
Subaru DL/GL .....	117
Subaru GL 4WD .....	084
Toyota Corolla .....	096
Toyota Tercel .....	098
Volkswagen Fox .....	126
Volkswagen Golf .....	101
Volkswagen Jetta .....	131
<b>Two-Door Models</b>	
<b>Large:</b>	
Buick LeSabre .....	115
Ford Thunderbird .....	072
Mercury Cougar .....	093
Oldsmobile 98 .....	099
<b>Midsized:</b>	
Buick Regal .....	088
Buick Skyhawk .....	101
Buick Somerset/Skylark .....	091
Chevrolet Beretta .....	121
Chevrolet Cavalier .....	112
Chrysler LeBaron .....	116
Dodge Aries .....	075
Ford Tempo .....	091
Honda Accord .....	116
Honda Prelude .....	119
Mercury XR4Ti .....	117



TABLE—Continued

	Collision Loss
Oldsmobile Calais .....	105
Oldsmobile Cutlass Ciera .....	094
Oldsmobile Cutlass Supreme .....	084
Plymouth Reliant .....	077
Pontiac Grand Am .....	099
Pontiac Grand Prix .....	087
Pontiac Sunbird .....	117
Small:	
Acura Integra .....	138
Chevrolet Spectrum .....	121
Chevrolet Sprint .....	114
Dodge Daytona .....	142
Dodge Colt .....	118
Dodge Shadow .....	117
Ford Escort .....	129
Ford Festiva .....	102
Ford Probe .....	134
Honda Civic .....	099
Hyundai Excel .....	112
Isuzu I-Mark .....	129
Mazda MX-6 .....	141
Mazda 323 .....	092
Mercury Tracer .....	114
Mitsubishi Starion .....	341
Nissan Pulsar .....	144
Nissan Sentra .....	133
Nissan 240SX .....	169
Plymouth Conquest .....	344
Plymouth Sundance .....	112
Pontiac LeMans .....	143
Saab 900 Turbo, S .....	182
Subaru DL/GL .....	111
Subaru GL 4WD .....	113
Subaru Justy .....	097
Subaru XT Coupe .....	154
Toyota Celica .....	144
Toyota Corolla .....	139
Toyota Tercel .....	102
Volkswagen Fox .....	116
Volkswagen Golf .....	102
Volkswagen GTI .....	169
Yugo .....	099

TABLE—Continued

	Collision Loss
<b>Sports &amp; Specialty Models</b>	
Large:	
BMW 735i .....	186
Cadillac Brougham .....	083
Cadillac DeVille 2D .....	104
Cadillac Fleetwood/DeVille 4D .....	083
Lincoln Town Car .....	083
Mercedes SEL/SDL Series .....	149
Mercedes 260E/300D/E .....	161
Midsize:	
Acura Legend 4D .....	102
Austin Roy Sterling 825/827 .....	118
BMW 325i Conv .....	177
BMW 300 Series 2D .....	192
BMW 300 Series 4D .....	249
Buick Riviera .....	103
Cadillac Eldorado .....	103
Cadillac Seville .....	098
Chevrolet Camaro .....	153
Chevrolet Cavalier Conv .....	116
Chrysler LeBaron Conv .....	117
Ford Mustang .....	168
Ford Mustang Conv .....	142
Lincoln Continental .....	071
Lincoln Mark VII .....	127
Mercedes 190D/E .....	150
Oldsmobile Toronado .....	112
Pontiac Firebird .....	158
Saab 9000 .....	152
Toyota Supra .....	182
Volvo 740/760 SW .....	089
Volvo 740/760 4D .....	110
Small:	
Chevrolet Corvette .....	155
Chevrolet Corvette Conv .....	122
Honda Civic CRX .....	156
Mercedes 560SL Conv .....	154
Nissan 300ZX .....	142
Nissan 300ZX2+2 .....	155
Porsche 944 Coupe .....	270
Toyota Celica Conv .....	142
Toyota MR2 .....	141

TABLE—Continued

	Collision Loss
Volkswagen Cabriolet .....	129

Most car models are listed, but some are not reported because there are relatively few of them on U.S. roads and, hence, insufficient data to compute collision loss results.

Consumers are advised that differences in insurance premiums for collision coverage only partially reflect damage susceptibility of cars, and premiums also are dependent on other factors, mainly vehicle cost or appraised value, driver characteristics and/or geographic location in which the vehicle is driven.

Premiums for other insurance coverage (such as liability, personal injury, and comprehensive) do not reflect differences in vehicle damage susceptibility or crashworthiness. Consumers are also advised that information presented is based on the historical performance of the models listed, new models are not represented, comparisons may not accurately reflect the performance of models that have been modified substantially, and that different insurance companies are likely to have different premiums for the same vehicle.

Issued on November 1, 1991.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 91-26854 Filed 11-4-91;11:54 am]

BILLING CODE 4910-59-M



# Notices

Federal Register

Vol. 56, No. 216

Thursday, November 7, 1991

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## AGENCY FOR INTERNATIONAL DEVELOPMENT

### Public Information Collection Requirements Submitted to OMB for Review

The Agency for International Development (A.I.D.) submitted the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Comments regarding these information collections should be addressed to the OMB reviewer listed at the end of the entry no later than ten days after publication. Comments may also be addressed to, and copies of the submissions obtained from the Reports Management Officer, Fred D. Allen, (703) 875-1573, FA/AS/ISS, room 1209B, SA-14, Washington, DC 20523-1413.

*Date Submitted:* October 24, 1991.

*Submitting Agency:* Agency for International Development.

*OMB Number:* 0412-0012.

*Form Number:* A.I.D. 282.

*Type of Submission:* Renewal.

*Title:* Supplier's Certificate and Agreement with the Agency for International Development—Invoice and Contract Abstract.

*Purpose:* A.I.D. finances goods and related services under its Commodity Import Programs (CIPs) which are contracted for by public and private entities in the countries receiving the A.I.D. assistance. Since A.I.D. is not a party to these contracts, A.I.D. needs some means to collect information directly from the suppliers of the goods and related services and enable A.I.D. to take appropriate action against them in the event they do not comply with the applicable regulations. A.I.D. does this by securing from the suppliers, as a condition for the disbursement of funds, a certificate and agreement with A.I.D. which contains appropriate representations by the supplier.

### Annual Reporting Burden

*Respondents:* 760; *Annual Responses:* 6; *Average Hours per Response:* .50; *Burden Hours:* 2,250.

*Reviewer:* Lin Liu (202) 395-7340, Office of Management and Budget, room 3208, New Executive Office Building, Washington, DC 20503.

*Dated:* October 28, 1991.

Elizabeth Baltimore,

Information Support Services Division.

[FR Doc. 91-26889 Filed 11-6-91; 8:45 am]

BILLING CODE 6116-01-M

## DEPARTMENT OF AGRICULTURE

### Forms Under Review by Office of Management and Budget

November 1, 1991.

The Department of Agriculture has submitted to OMB for review the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35) since the last list was published. This list is grouped into new proposals, revisions, extensions, or reinstatements. Each entry contains the following information:

(1) Agency proposing the information collection; (2) Title of the information collection; (3) Form number(s), if applicable; (4) How often the information is requested; (5) Who will be required or asked to report; (6) An estimate of the number of responses; (7) An estimate of the total number of hours needed to provide the information; (8) Name and telephone number of the agency contact person.

Questions about the items in the listing should be directed to the agency person named at the end of each entry. Copies of the proposed forms and supporting documents may be obtained from: Department Clearance Officer, USDA, OIRM, room 404-W Admin. Bldg., Washington, DC 20250, (202) 447-2118.

### New Collection (Emergency)

- Food and Nutrition Service. Evaluation of Maryland's Expanded Electronic Benefit Transfer Program. One time survey. State or local governments; Federal agencies or employees; 28,694 responses; 3,317 hours. Margaret Andrews (703) 756-3115.

### Reinstatement

- Farmers Home Administration. 7 CFR 1951-R, Rural Development Loan Fund Servicing FmHA 1951-4. On occasion; quarterly; semi-annually; annually.

State or local governments; businesses or other for-profits; non-profit institutions; small businesses or organizations; 904 responses; 4,708 hours.

Jack Holston (202) 720-9736.

- Farmers Home Administration. 7 CFR 1951-N, Servicing Cases Where Unauthorized Loan or Other Financial Assistance was Received—Multiple Family Housing.

On occasion.

Individuals or households; State or local governments; farms; businesses or other for-profit; non-profit institutions; small businesses or organizations; 700 responses; 800 hours.

Jack Holston (202) 720-9736.

Donald E. Hulcher,

Deputy Departmental Clearance Officer.

[FR Doc. 91-26852 Filed 11-6-91; 8:45 am]

BILLING CODE 3410-01-M

### Office of the Secretary

#### Members of Performance Review Boards

**AGENCY:** U.S. Department of Agriculture.

**ACTION:** Notice.

**SUMMARY:** This document cancels the list of Performance Review Board members published November 6, 1990, 55 FR 46692 and gives notice of new Performance Review Board members.

**EFFECTIVE DATE:** Upon publication in the Federal Register.

#### FOR FURTHER INFORMATION CONTACT:

Mary Ellen Dix, Chief, Compensation, Employment and Performance Management Staff, Office of Personnel, U.S. Department of Agriculture, 14th Street and Independence Avenue, SW., Washington, DC 20250, (202) 720-2830.

The membership of the U.S. Department of Agriculture's Performance Review Boards For Fiscal Year 1991 include:

Stephen N. Abrams  
LaVerne G. Ausman  
Franklin E. Bailey  
Catherine A. Bertini  
Angela V. Bracht



George A. Braley  
Sally I. Buikema  
Gary C. Byrne  
John B. Campbell  
Ann E. Carey  
Mary E. Carter  
James E. Cason  
Charles E. Caudill  
Stephen Censky  
David T. Chen  
Cynthia Z. Clark  
Keith J. Collins  
Kathleen H. Connelly  
Richard T. Crowder  
Stephen B. Dewhurst  
James R. Donald  
John C. Foltz  
James R. Franks  
James Frazier, Jr.  
John E. Frydenlund  
Bruce L. Gardner  
William E. Gardner, Jr.  
Charles R. Gillum  
John Golden  
Earl C. Hadlock  
Daniel D. Haley  
James V. Hansen  
Paula F. Hayes  
Glenn J. Hertzler, Jr.  
Michael Hill  
Charles R. Hilty  
Wilson S. Horne  
Jacquelyn Howard  
William J. Hudnall, Jr.  
Jo Ann C. Jenkins  
Allan S. Johnson  
Myron D. Johnsrud  
John P. Jordan  
James Michael Kelly  
John E. Lee, Jr.  
Diane R. Liesman  
Linda P. Massaro  
Terry L. Medley  
Robert B. Melland  
James R. Moseley  
Harry C. Mussman  
William E. O'Connor  
Daniel Peyser  
Marvin Pierce  
Ronald Plowman  
Ronald J. Prucha  
Allan C. Raul  
Katherine H. Reichelderfer  
William J. Richards  
Sue Ann Ritchko  
F. Dale Robertson  
Roger D. Runnigen  
Jeffrey Rush, Jr.  
Judith A. Segal  
Carol M. Seymour  
Robert E. Sherman  
Larry B. Slagle  
Dallas R. Smith  
Jo Ann R. Smith  
Leon Snead  
Scott Steele  
John A. Stevenson  
Daniel A. Sumner  
Alejandro B. Thiermann  
Derek Vander Schaaf  
Roland R. Vautour  
Ann M. Veneman  
Lawrence Wachs  
Jettie B. Wilds, Jr.  
Edward M. Wilson  
Larry Wilson, Jr.

#### Alternates

Duane C. Acker  
John H. Arnesen  
Gerald A. Bange  
Fred S. Barrett, Jr.  
Donald M. Bay  
Louis G. Bennett  
Keith D. Bjerke  
Elizabeth I. Board  
Calen S. Bridge  
Cameron D. Bruemmer  
John H. Beuter  
Kenneth L. Deavers  
F. Paul Dickerson  
Rachel Dobscha-Scioscia  
Robert Franco  
David R. Gallart  
Phyllis R. Gault  
Mitchell R. Geasler  
Clare I. Harris  
Joseph H. Howard  
Lonnice J. King  
Edward B. Knippling  
B. Glen Lee  
Joseph J. Leo  
George M. Leonard  
Michael Liu  
Philip L. Mackie  
Gary K. Madson  
Charles R. Miller  
John A. Miranowski  
Betty Jo Nelsen  
Floy E. Payton  
David Rector  
Virgil M. Rosendale  
Charles Rumburg  
Randall E. Torgerson  
Jane A. Wittmeyer

Dated: November 5, 1991.

Edward Madigan,

Secretary.

[FR Doc. 91-27040 Filed 11-5-91; 3:29 pm]

BILLING CODE 3410-96-M

#### Agricultural Research Service

##### Intent to Grant an Exclusive License

**AGENCY:** Agricultural Research Service, USDA.

**ACTION:** Notice of intent.

**SUMMARY:** Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant a partially exclusive license to Plato Industries, Inc., Houston, Texas, on U.S. Patent Application Serial No. 07/473,757, "A Plastic Bait Composition for Attracting and Killing Crops Pests," filed February 2, 1990, and on U.S. Patent Application Serial No. 07/592,946, "Insect Control Using Insect Attracticide Compositions," filed October 4, 1990. Notices of Availability were given on September 20, 1990, and January 31, 1991, respectively.

**DATES:** Comments must be received by January 6, 1991.

**ADDRESSES:** Send comments to: USDA-ARS—Office of Cooperative

Interactions, Beltsville Agricultural Research Center, Baltimore Boulevard, Building 005, room 403, BARC-W, Beltsville, Maryland 20705-2350.

#### FOR FURTHER INFORMATION CONTACT:

M. Ann Whitehead of the Office of Cooperative Interactions at the Beltsville address given above; telephone: 301/344-2786, (FTS) 344-2786.

**SUPPLEMENTARY INFORMATION:** The USDA-ARS intends to grant to Plato Industries, Inc., a partially exclusive license to practice the aforementioned inventions. Patent rights to these inventions are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license these inventions as Plato Industries, Inc., has submitted a complete and sufficient application for a license, promising therein to bring the benefits of said inventions to the U.S. public.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7a. The prospective exclusive license may be granted unless, within sixty days from the date of this published Notice, ARS receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

William H. Tallent,

Assistant Administrator.

[FR Doc. 91-26915 Filed 11-6-91; 8:45 am]

BILLING CODE 3410-03-M

#### Animal and Plant Health Inspection Service

[Docket No. 91-146]

##### Availability of Proposed Revision of Veterinary Biologics Memorandum No. 800.65 Concerning Eggs for Production of Animal Biological Products

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** This document provides notice that a proposed revision of Veterinary Biologics Memorandum No. 800.65, Eggs for Production of Animal Biological Products, issued January 24, 1985, is available for comment. The proposed memorandum differs from the original memorandum in that it would provide for a single standard for embryonated chicken eggs for use with both live and killed biological products.



**DATES:** Consideration will be given only to comments received on or before January 6, 1991.

**ADDRESSES:** Copies of the proposed revision of Veterinary Biologics Memorandum No. 800.65 are available upon request by writing to the person listed under "**FOR FURTHER INFORMATION CONTACT**". To ensure that your written comments are considered, send an original and three copies to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 91-146. Comments received may be inspected at room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

**FOR FURTHER INFORMATION CONTACT:** Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, room 838, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8245.

**SUPPLEMENTARY INFORMATION:** The Animal and Plant Health Inspection Service (APHIS) administers and enforces the Virus-Serum-Toxin Act (the Act), as amended (21 U.S.C. 151-159). The regulations issued pursuant to the Act are intended to ensure that veterinary biological products meet standards of purity, safety, potency, and efficacy. The regulations under 9 CFR 113.50 provide, among other things, that the ingredients used in a licensed biological product should meet accepted standards of purity and quality. APHIS has proposed a revision of Veterinary Biologics Memorandum No. 800.65 which contains guidelines for producers of veterinary biologics regarding eggs which are used for the production of veterinary biologics. The revised memorandum is intended to supersede Memorandum 800.65, issued January 24, 1985, to ensure that only the highest quality of eggs are used in the preparation of vaccines. The revised memorandum recommends a single standard for embryonated chicken eggs used for the production of both live and killed biological products. Such eggs would be derived from a rigorously tested, specific-pathogen-free (SPF) flock as described in the proposed memorandum. The agency has determined that the 1985 memorandum should be revised for the following two reasons.

1. Memorandum No. 800.65 was issued in response to an emergency shortage of eggs from SPF flocks for vaccine production and recommended a lower quality standard for eggs used in the production of killed biological products. Prior to 1985, only one class of eggs were used for the production of both live and killed vaccines. Since the emergency situation no longer exists, the provision for a different quality of egg for production of killed vaccine is no longer necessary or desirable.

2. The 1985 memorandum did not include guidelines concerning either testing of the final killed product, or the validation of the inactivation procedure, despite an increased risk of contamination of the killed product by extraneous agents potentially derived from the lower quality egg. In the proposed revision of the memorandum, the return to the use of a higher quality egg for both live and killed products obviates the need for such testing requirements, while still ensuring a pure final product.

Other changes in the proposed revision of the memorandum include, but are not limited, to the following:

1. The memorandum has been revised to include testing for avian adenoviruses (group I, serotype 1-12; group II; EDS 76 virus), chicken anemia virus, infectious bronchitis virus (Arkansas and JMK strains), Marek's disease, and reticuloendotheliosis virus. The proposed memorandum reflects more accurately current field disease situations.

2. The proposed memorandum recommends that flocks be serologically monitored for infectious disease on either a weekly or monthly basis, with a minimum of 60 birds sampled per week. The weekly testing permits more rapid detection of disqualifying diseases with the result that fewer eggs need to be discarded by both the egg and vaccine producer in the event of a disease outbreak in the flock producing the eggs.

3. The proposed memorandum recommends 50 rather than 100% initial flock testing for most horizontally transmitted diseases. The effect would be a reduction in labor, materials, and expense required for initial flock testing without affecting the efficiency of disease monitoring.

4. The proposed memorandum describes actions that should be taken by a production facility in order to ensure final vaccine purity in the event of a disease outbreak in the source flock.

**Authority:** 21 U.S.C. 151-159; 7 CFR 2.17, 2.51 and 371.2(d).

Done in Washington, DC, this 31st day of October 1991.

Robert Melland,

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 91-26805 Filed 11-6-91; 8:45 am]

BILLING CODE 3410-34-M

[Docket No. 91-151]

**Availability of List of U.S. Veterinary Biological Product and Establishment Licenses, and U.S. Veterinary Biological Product Permits, Issued, Suspended, Revoked, or Terminated**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** This notice is to advise the public of veterinary biological product and establishment licenses and veterinary biological product permits that were issued, suspended, revoked, or terminated by the Animal and Plant Health Inspection Service, during the months of August and September 1991. These actions have been taken in accordance with the regulations issued pursuant to the Virus-Serum-Toxin Act. The purpose of this notice is to notify interested persons of the availability of a list of these actions and advise interested persons that they may request to be placed on a mailing list to receive the listing.

**FOR FURTHER INFORMATION CONTACT:** Joan Montgomery, Program Assistant, Veterinary Biologics, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-4873. For copies of the list or to be placed on the mailing list, write to Ms. Montgomery at the above address.

**SUPPLEMENTARY INFORMATION:** The regulations in 9 CFR part 102, "Licenses For Biological Products," require that every person who prepares certain biological products that are subject to the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*) shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product License. The regulations set forth the procedures for applying for a license, the criteria for determining whether a license shall be issued, and the form of the license.

The regulations in 9 CFR part 102 also require that each person who prepares biological products that are subject to the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*) shall hold a U.S. Veterinary Biologics Establishment License. The regulations set forth the procedures for



applying for a license, the criteria for determining whether a license shall be issued, and the form of the license.

The regulations in 9 CFR part 104, "Permits for Biological Products," require that each person importing biological products shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product Permit. The regulations set forth the procedures for applying for a permit, the criteria for determining whether a permit shall be issued, and the form of the permit.

The regulations in 9 CFR parts 102 and 105 also contain provisions concerning the suspension, revocation, and termination of U.S. Veterinary Biological Product Licenses, U.S. Veterinary Biologics Establishment and U.S. Veterinary Biological Product Permits.

Each month the Veterinary Biologics section of Biotechnology, Biologics, and Environmental Protection prepares a list of licenses and permits that have been issued, suspended, revoked, or terminated. This notice announces the availability of the lists for August and September 1991. The list is also mailed on a regular basis to interested persons. To be placed on the mailing list you may call or write the person designed under **FOR FURTHER INFORMATION CONTACT.**

Done in Washington, DC, this 31st day of October.

**Robert Melland,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 91-28806 Filed 11-6-91; 8:45 am]

BILLING CODE 3410-34-M

## Cooperative State Research Service

### Committee of Nine; Meeting

In accordance with the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92-463, 86 Stat. 770-776), the Cooperative State Research Service announces the following meeting:

**Name:** Committee of Nine.

**Date:** December 5-6, 1991.

**Time:** 8:30 a.m.-5 p.m.

**Place:** Administration Bldg. Louisiana State University, Baton Rouge, Louisiana.

**Type of Meeting:** Open to the public.

Persons may participate in the meeting as time and space permit.

**Comments:** The public may file written comments before or after the meeting with the contact person listed below.

**Purpose:** To evaluate and recommend proposals for cooperative research on problems that concern agriculture in two or more States, and to make recommendations for allocation of regional research funds appropriated by Congress under the Hatch Act for research at the State Agricultural Experiment Stations.

**Contact Person for Agenda and More Information:** Dr. Edward M. Wilson, Executive Secretary, U.S. Department of Agriculture, Cooperative State Research Service, room 328, Aerospace Building, Washington, DC 20250, Telephone: 202-401-6040.

Done at Washington, DC this 24th day of October, 1991.

**John Patrick Jordan,**

*Administrator, Cooperative State Research Service.*

[FR Doc. 91-26916 Filed 11-6-91; 6:45 am]

BILLING CODE 3410-22-M

## Forest Service

### Grand Island Advisory Commission; Meeting

**AGENCY:** Forest Service, USDA.

**ACTION:** Grand Island Advisory Commission meeting.

**SUMMARY:** The Grand Island Advisory Commission will meet on November 24 at 1 at the Munising Ranger District Office in Munising, Michigan. An agenda for the two day meeting will consist of Update on East Channel Lighthouse past and future, Michigan State Update on surveys being done, update from Core Team on suggested changes in alternatives and further discussion on a new alternative.

Interested members of the public are encouraged to attend.

**FOR FURTHER INFORMATION CONTACT:**

Direct questions about this meeting to Art Easterbrook, Staff Officer, Hiawatha National Forest, 2727 N. Lincoln Road, Escanaba, MI 49829, (906) 786-4062.

Dated: November 1, 1991.

**Arthur L. Easterbrook,**

*Acting Forest Supervisor.*

[FR Doc. 91-26863 Filed 11-6-91; 8:45 am]

BILLING CODE 3410-11-M

## Soil Conservation Service

### Black Creek Watershed Johnston and Wake Counties, NC

**AGENCIES:** North Carolina Department of Environment, Health, and Natural Resources and the United States Department of Agriculture, Soil Conservation Service.

**ACTION:** Notice of finding of no significant impact.

**SUMMARY:** Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council of Environmental Quality Guidelines (40 CFR part 1500); and the Soil Conservation Service Guidelines (7 CFR part 650); the Division of Soil and Water

Conservation, North Carolina Department of Environment, Health, and Natural Resources and the Soil Conservation Service, United States Department of Agriculture, give notice that an environmental impact statement is not being prepared for the Black Creek Watershed, Johnston and Wake Counties, North Carolina.

### FOR FURTHER INFORMATION CONTACT:

David W. Sides, Director, Division of Soil and Water Conservation, North Carolina Department of Environment, Health and Natural Resources, P.O. Box 27687, Raleigh, North Carolina 27611, telephone (919) 733-2302 or Bobbye J. Jones, State Conservationist, Soil Conservation Service, 4405 Bland Road, suite 205, Raleigh, North Carolina 27609, telephone (919) 790-2888.

**SUPPLEMENTARY INFORMATION:** The Environmental Assessment of this federally assisted action indicates that the project will not cause significant adverse local, regional, or national impacts on the environment. As a result of these findings, Bobbye J. Jones, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The project concerns a plan for watershed protection. The planned works of improvement include accelerated technical and financial assistance to apply land treatment measures on 9,000 acres of cropland and install 14 animal waste management systems.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy request at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting David W. Sides.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904—Watershed Protection and Flood Prevention—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials.)

Dated: October 28, 1991.

**Bobbye J. Jones,**

*State Conservationist.*

[FR Doc. 91-26880 Filed 11-6-91; 8:45 am]

BILLING CODE 3410-16-M



**CIVIL RIGHTS COMMISSION****Agenda and Public Meeting of the District of Columbia State Advisory Committee**

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the District of Columbia State Advisory Committee to the Commission will convene at 12:30 p.m. and adjourn at 3 p.m. on Wednesday, December 11, 1991, U.S. Commission on Civil Rights, Conference Room 512, 1121 Vermont Avenue, NW., Washington, DC 20425. The purpose of the meeting is to conduct program planning activity.

Persons desiring additional information, or planning a presentation to the Committee, should contact John I. Binkley, Director, Eastern Regional Division at (202) 523-5264, TDD (202) 376-8117. Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Division at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, November 1, 1991.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 91-26881 Filed 11-6-91; 8:45 am]

BILLING CODE 6335-01-M

**Agenda and Public Meeting of the New Jersey State Advisory Committee**

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the New Jersey State Advisory Committee to the Commission will convene at 2 p.m. and adjourn at 5 p.m. on Monday, December 9, 1991, Quality Inn, Conference Center—Board Room, Route 1, South, North Brunswick, NJ 08902. The purpose of the meeting is to conduct program planning and review a draft report on law enforcement practices in New Jersey.

Persons desiring additional information, or planning a presentation to the Committee, should contact John I. Binkley, Director, Eastern Regional Division at (202) 523-5264, TDD (202) 376-8117. Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Division at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, November 1, 1991.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 91-26882 Filed 11-6-91; 8:45 am]

BILLING CODE 6335-01-M

**Agenda and Notice of Public Meeting of the Tennessee State Advisory Committee**

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Tennessee Advisory Committee to the Commission will convene at 2 p.m. and adjourn at 4 p.m. on Tuesday, December 10, 1991, at the Doubletree Hotel, 2 Sovran Plaza (4th Ave. at Union Street), Nashville, Tennessee 37239. The purpose of the meeting is: (1) To orientate the SAC; (2) to discuss the status of the Commission; (3) hear a report on civil rights progress and/or problems in the State; (4) to discuss plans for a project for Fiscal Year 1992.

Persons desiring additional information, or planning a presentation to the Committee should contact Tennessee Committee Chairperson Gail Neuman (615/459-1414) or Bobby D. Doctor, Regional Director, Southern Regional Office of the U.S. Commission on Civil Rights at (404/730-2476, TDD 404/730-2481). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Southern Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 91-26810 Filed 11-6-91; 8:45 am]

BILLING CODE 6335-01-M

**Agenda and Notice of Public Meeting of the Wisconsin Advisory Committee**

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Wisconsin Advisory Committee to the Commission will be held from 1 p.m. until 5 p.m. on Wednesday, December 4, 1991, at the Marc Plaza Hotel, 509 West Wisconsin Avenue, Milwaukee, Wisconsin. The purpose of this meeting is for the Committee to receive briefings on

equality of policy protection and high the rate of dropouts among minority college students.

Persons desiring additional information should contact James L. Baughman, Committee Chairperson at (608) 262-3690 or Constance M. Davis, Regional Director of the Midwestern Regional Office, U.S. Commission on Civil Rights, at (312) 353-8311. Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Division at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 31, 1991.

**Carol Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 91-26811 Filed 11-6-91; 8:45 am]

BILLING CODE 6335-01-M

**DEPARTMENT OF COMMERCE****Bureau of Export Administration****Automated Manufacturing Equipment Technical Advisory Committee; Closed Meeting**

A meeting of the Automated Manufacturing Equipment Technical Advisory Committee will be held December 5, 1991, 9 a.m. to 3 p.m., in the Herbert C. Hoover Building, room 1617F, 14th Street & Pennsylvania Avenue, NW., Washington, DC. The Committee advises the Office of Technology and Policy Analysis with respect to technical questions that affect the level of export controls applicable to automated manufacturing equipment and related technology.

The Committee will meet only in Executive Session to discuss matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on January 5, 1990, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, that the series of meetings of the Committee and of any Subcommittees thereof, dealing with the classified materials listed in 5 U.S.C., 552b(c)(1) shall be exempt from the provisions relating the public meetings found in section 10(a)(1) and (a)(3), of the Federal Advisory Committee Act. The remaining series of



meetings or portions thereof will be open to the public.

A copy of the Notice of Determination to close meetings or portions of meetings of the Committee is available for public inspection and copying in the Central Reference and Records Inspection Facility, room 6628, U.S. Department of Commerce, Washington, DC 20230. For further information, contact Lee Ann Carpenter on (202) 377-2583.

Dated: November 1, 1991.

Betty A. Ferrell,

Director, Technical Advisory Committee Staff.

[FR Doc. 91-26945 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-DT-M

### Electronic Instrumentation Technical Advisory Committee; Partially Closed Meeting

A meeting of the Electronic Instrumentation Technical Advisory Committee will be held December 3, 1991, 9 a.m., in the Herbert C. Hoover Building, room 1617F, 14th & Pennsylvania Avenue, NW., Washington, DC. The Committee advises the Office of Technology and Policy Analysis with respect to technical questions that affect the level of export controls applicable to electronics and related equipment and technology.

#### Agenda:

##### General Session

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Discussion of COCOM Core List export controls.
4. Discussion of nuclear nonproliferation and missile tech controls.

##### Executive Session

5. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent that time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials two weeks prior to the meeting date to the following address: Lee Ann Carpenter, TAC Staff/BXA/Rm. 1621, U.S. Department of Commerce, 14th & Pennsylvania Ave., NW., Washington, DC 20230.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on January 5, 1990, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, that the series of meetings of the Committee and of any Subcommittees thereof, dealing with the classified materials listed in 5 U.S.C., 552b(c)(1) shall be exempt from the provisions relating to public meetings found in section 10(a)(1) and (a)(3), of the Federal Advisory Committee Act. The remaining series of meetings or portions thereof will be open to the public.

A copy of the Notice of Determination to close meetings or portions of meetings of the Committee is available for public inspection and copying in the Central Reference and Records Inspection Facility, room 6628, U.S. Department of Commerce, Washington, DC 20230. For further information or copies of the minutes, contact Lee Ann Carpenter on (202) 377-2583.

Dated: November 11, 1991.

Betty Anne Ferrell,

Director, Technical Advisory Committee Staff.

[FR Doc. 91-26946 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-DT-M

### Telecommunications Equipment Technical Advisory Committee; Partially Closed Meeting

A meeting of the Telecommunications Equipment Technical Advisory Committee will be held December 4, 1991, 9:30 a.m., in the Herbert C. Hoover Building, room 1617F, 14th & Pennsylvania Avenue, NW., Washington, DC. The Committee advises the Office of Technology and Policy Analysis with respect to technical questions that affect the level of export controls applicable to telecommunications and related equipment and technology.

#### Agenda:

##### General Session

1. Opening remarks by the Chairman.
2. Approval of minutes.
3. Election of Chairman.
4. Presentation of papers or comments by the public.
5. Report on status of U.S. implementation of Core List.
6. Discussion of industry reaction to Core List and recommendations for future changes.

##### Executive Session

7. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent that time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials two weeks prior to the meeting date to the following address: Lee Ann Carpenter, Technical Support Staff, OPA/BXA, room 1621, U.S. Department of Commerce, 14th & Pennsylvania Ave., NW., Washington, DC 20230.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on January 5, 1990, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, that the series of meetings of the Committee and of any Subcommittees thereof, dealing with the classified materials listed in 5 U.S.C., 552b(c)(1) shall be exempt from the provisions relating to public meetings found in section 10(a)(1) and (a)(3), of the Federal Advisory Committee Act. The remaining series of meetings or portions thereof will be open to the public. A copy of the Notice of Determination to close meetings or portions of meetings of the Committee is available for public inspection and copying in the Central Reference and Records Inspection Facility, room 6628, U.S. Department of Commerce, Washington, DC 20230. For further information or copies of the minutes, contact Lee Ann Carpenter on (202) 377-2583.

Dated: November 1, 1991.

Betty Anne Ferrell,

Director, Technical Advisory Committee Unit.

[FR Doc. 91-26947 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-DT-M

### International Trade Administration

[A-475-601]

### Certain Brass Sheet and Strip From Italy; Preliminary Results of Antidumping Duty Administrative Reviews

**AGENCY:** International Trade Administration, Import Administration, Department of Commerce.

**ACTION:** Notice of preliminary results of antidumping duty administrative reviews.



**SUMMARY:** In response to requests by petitioner and respondent, the Department of Commerce is conducting two administrative reviews of the antidumping duty order on certain brass sheet and strip from Italy. The reviews cover shipments of this merchandise to the United States from one exporter during the periods of August 22, 1986 through February 29, 1988, and March 1, 1989 through February 28, 1990. As a result of these reviews, we preliminarily determine that dumping margins exist. Interested parties are invited to comment on the preliminary results of these administrative reviews.

**EFFECTIVE DATE:** November 7, 1991.

**FOR FURTHER INFORMATION CONTACT:** James Rice or Richard Weible, Office of Agreements Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th St. and Constitution Ave., NW., Washington, DC 20230; telephone (202) 377-3793.

**SUPPLEMENTARY INFORMATION:**

**Background**

On March 8, 1987, the Department published in the *Federal Register* an antidumping duty order in brass sheet and strip from Italy (52 FR 6997). On March 8, 1988, we published in the *Federal Register* a Notice of Opportunity to Request an Administrative Review of this order for the period from August 22, 1986 through February 29, 1988 (53 FR 7383). On March 31, 1988, we received a request for an administrative review for this period from petitioners, American Brass, Bridgeport Brass Corporation, Hussey Copper Ltd., the Miller Company, North Coast Brass & Copper Co., Olin Corporation-Brass Group, Revere Copper Products, Inc., International Association of Machinists and Aerospace Workers, International Union-Allied Industrial Workers of America (AFL-CIO), Mechanics Educational Society of America (Local 56), and the United Steelworkers of America (AFL-CIO/CLC). We initiated this review on April 27, 1988 (53 FR 15083).

On March 28, 1990, the Department published in the *Federal Register* a Notice of Opportunity to Request an Administrative Review for the period from March 1, 1989 through February 28, 1990 (55 FR 11417). The Department received a request for an administrative review covering this period from the respondent, Europa Metalli LMI S.p.A. (LMI). We initiated this review on April 27, 1990 (55 FR 17792). The Department is now conducting these two administrative reviews in accordance with section 751 of the Tariff Act of

1930, as amended (the Act). Each review covers one producer/exporter (LMI) of brass sheet and strip from Italy to the United States.

**Scope of the Review**

The products covered by these reviews are shipments of brass sheet and strip, other than leaded brass and tin brass sheet and strip, from Italy. The chemical composition of the products under investigation is currently defined in the Copper Development Association (C.D.A.) 200 series or the Unified Numbering System (U.N.S.) C2000 series. Products whose chemical composition are defined by other C.D.A. or U.N.S. series are not covered by these reviews. The physical dimensions of the products covered by these reviews are brass sheet and strip of solid rectangular cross section, over 0.006 inch (0.15 millimeter) but not over 0.188 inch (4.8 millimeters) in finished thickness or gauge, regardless of width, whether coiled, wound on reels (traverse wound), or cut-to-length. Until January 1, 1989, this merchandise was classifiable under item numbers 612.3960, 612.3982, and 612.3986 of the Tariff Schedules of the United States Annotated (TSUSA). Since that date, brass sheet and strip have been classifiable under Harmonized Tariff System (HTS) item numbers 7409.21.00.50, 7409.21.00.75, 7409.21.00.90, 7409.29.00.50, 7409.29.00.75, and 7409.29.00.90. HTS and TSUSA item numbers are provided for convenience and customs purposes. The written product description remains dispositive.

**Preliminary Results of the Reviews**

In both reviews Petitioners alleged that LMI's home market sales were made at less than the cost of production ("COP"). We determined that both allegations were sufficient and initiated below cost investigations. We requested that LMI provide monthly average material costs for copper and zinc because the costs of these raw materials fluctuated significantly during both periods of review. LMI failed to provide monthly average material costs. As a result, we were unable to determine if LMI had sufficient sales at or above its COP in the home market to provide a basis for establishing foreign market value ("FMV"). Therefore, the Department established FMV on the basis on constructed value ("CV"), using the best information available, in accordance with section 776(c) of the Act.

For CV, we calculated monthly average costs for brass based upon the prices of copper and zinc published by the London metal Exchange ("LME") on the first, fifteenth, and last day of each

month (or nearest trading day). We used this method for calculating material cost because LMI failed to adequately report its actual material acquisition costs. In addition, Petitioner used monthly LME prices of copper and zinc to construct estimated material cost in its below cost sales allegation. This average monthly material cost was then adjusted to account for the various alloys of brass sold in the United States (ranging from 60 percent copper and 40 percent zinc to 85 percent copper and 15 percent zinc). We also adjusted CV to reflect a loss (or yield) rate incurred during the manufacturing process, and added a raw material transportation charge, which is not included in the daily LME price quotations. We accepted LMI's fabrication costs as reported in the COP questionnaire response. We used LMI's reported general and administrative expenses, which were greater than the statutory minimum ten percent of the sum of the material and fabrication costs. Finally, we added the statutory minimum of eight percent for profit and adjusted for LMI's reported U.S. packing costs and credit expense.

We based United States price on purchase price where sales were made directly to unrelated parties, and through commissionaires, in accordance with section 772(b) of the Act. We used purchase price as defined in section 772 of the Act, because brass sheet and strip was sold to unrelated purchasers in the United States prior to importation into the United States, and because exporter's sales price ("ESP") methodology was not indicated by other circumstances. We calculated purchase price on the basis of packed c.&f., c.i.f., or f.o.b., delivered prices. We made deductions from purchase price (where appropriate) for brokerage and handling, ocean freight, marine insurance, Italian import duty, and inland freight.

As a result of our reviews, we preliminarily determine that the following margins exist:

Producer/ Exporter	Period of review	Percent margin
LMI.....	06/22/86-02/29/88	21.07
LMI.....	03/01/89-02/28/90	21.01

Parties to the proceeding may request disclosure within five days of the date of publication of this notice. Any interested party may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the date of publication of this preliminary notice or the first workday thereafter.

Case briefs and/or written comments from interested parties may be



submitted not later than 30 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to issues raised in the case briefs and comments, may be filed not later than 37 days after the date of publication. The Department will publish the final results of these administrative reviews, including the results of its analysis of issues raised in any such written comments or at a hearing.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and foreign market value may vary from the percentages stated above. The Department will issue appraisement instructions directly to the Customs Service.

The following deposit requirements will be effective upon publication of the final results of the reviews for all shipments of the subject merchandise from Italy entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for the reviewed company will be that established in the final results of the 1989-90 review; for merchandise exported by manufacturers or exporters not covered by this review but covered in the final determination of sales at less than fair value, the cash deposit rate will continue to be at the rate published in that final determination; (2) if the exporter is not a firm covered in this review or the original investigation, but the manufacturer is so covered, the cash deposit rate will be that established for the manufacturer of the merchandise in the final results of the 1989-90 review or in the original investigation of sales at less than fair value; (3) the cash deposit rate for all other exporters/producers shall be 5.44 percent. These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

These administrative reviews and this notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and § 353.22 of the Commerce Department's regulations (19 CFR 353.22).

Dated: October 31, 1991.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import Administration.

[FR Doc. 91-26954 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-DS-M

[A-428-013]

# **Cold-Rolled Stainless Steel Sheet From Germany; Preliminary Results of Antidumping Duty Administrative Review Determination**

**AGENCY:** International Trade Administration/Import Administration, Department of Commerce.

**ACTION:** Preliminary results of antidumping duty administrative review determination.

**SUMMARY:** The Department of Commerce has prepared these preliminary results of the antidumping duty administrative review determination of cold-rolled stainless steel sheet from Germany pursuant to a remand order from the U.S. Court of International Trade in *Krupp Stahl, A.G., et al. v. United States* (Slip Op. 91-31, April 9, 1991).

**EFFECTIVE DATE:** November 7, 1991.

**FOR FURTHER INFORMATION CONTACT:** Jackie Johnson or Wendy Frankel, Office of Agreements Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-3793.

## **SUPPLEMENTARY INFORMATION:**

### **Background**

In August 1983, the Department initiated a section 751 review of Krupp's entries.

Subsequently, on August 13, 1985, the Department published regulations which provided that in the absence of a request for review, antidumping duties would be assessed at the rate equal to the estimated duties deposited at the time of entry. See 50 FR 32556. On August 30, 1985, the Department notified the interested parties that they must request a review of Krupp's entries or they would be liquidated automatically at the 27 percent rate determined for the preliminary determination. Krupp requested the continuation of the review on October 18, 1985, but withdrew the request on July 26, 1986. On October 9, 1986, the Department discontinued the review with regard to Krupp and directed Customs to liquidate Krupp's entries at the rate in effect at the time of entry. Krupp subsequently challenged the Department's actions to liquidate Krupp's entries at that rate.

The U.S. Court of International Trade ruled in *Krupp Stahl* that the Department illegally applied its automatic assessment regulation to Krupp's December 1982 through June 1983 entries because the original less than fair value investigation was

initiated prior to the October 30, 1984, amendment to the Tariff Act and prior to the October 22, 1986, amendment to the effective date provision of the 1984 Act. Because the 1984 and 1986 amendments are not retroactive, the court held that Krupp was entitled to an automatic review of its entries.

## **Scope of the Review**

Imports covered by the review are shipments of cold-rolled stainless steel sheet whether or not corrugated or crimped and whether or not pickled; not cut, not pressed and not stamped to non-rectangular shape; not coated or plated with metal, and under 0.1875 inch in thickness and over 12 inches in width. Until January 1, 1989, this merchandise was classifiable under item number 607.9020 of the Tariff Schedules of the United States Annotated (TSUSA).

Since that date, this merchandise is classifiable under the Harmonized Tariff Schedules (HTS) item numbers 7219.32.00, 7219.33.00, 7219.34.00, 7219.35.00, 7219.90.00, 7200.20.10, and 7220.90.00. As was the case with the TSUSA numbers, the HTS numbers are provided for convenience and Customs purposes only. The written product description remains dispositive.

This review covers one manufacturer, (Krupp Stahl, A.G.) of cold-rolled stainless steel sheet from the Federal Republic of Germany for the review period December 17, 1982 to May 6, 1983.

## **Preliminary Results of the Review**

On July 31, 1991, we sent Krupp a questionnaire requesting information concerning its sales for the period December 17, 1982 through June 23, 1983. On August 16, 1991, Krupp requested an extension to respond to the Department's questionnaire. Krupp did not respond. Instead, it advised the Department on September 12, 1991, that in 1989 it had destroyed the records for the period of the review. The company noted that in 1983 it had responded to an earlier questionnaire covering this period. After sending a deficiency letter regarding this response, we did not act further on the responses because on July 26, 1986, Krupp withdrew its request for review.

We have reviewed the record and have only been able to locate the public version of the written portion of the questionnaire response and the July 20, 1984, response to our July 9, 1984, deficiency letter. This is insufficient information for purposes of conducting an administrative review. In any event and more importantly, since Krupp has



destroyed the records for this period of review, there would be no way for the Department to verify the accuracy or the completeness of the information in those responses. Because Krupp has failed to respond to the Department's July 31, 1991, questionnaire and because Krupp has destroyed the records needed to verify the adequacy of the information contained in the earlier response, the Department has used the best information otherwise available (BIA) for this review. As BIA for this company, the Department used the simple average of the rates provided in the petition which is 27 percent. This also was the rate assigned to Krupp for the preliminary determination (47 FR 56529).

Parties to the proceeding may request disclosure within 5 days of the date of the publication of this notice. Any interested parties may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the date of publication of this notice or the first workday thereafter.

Case briefs and/or written comments from interested parties may be submitted not later than 30 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to issues raised in the case briefs and comments, may be filed not later than 37 days after the date of publication. The Department will publish the final results of this administrative review, including the results of its analysis of issues raised in any such written comments or at a hearing.

On August 11, 1986, the Department published in the **Federal Register** (51 FR 28738) a notice of a revocation of the order, effective March 1, 1986. This administrative review covering the period December 17, 1982 to May 31, 1983, does not affect the revocation of the antidumping duty order. Therefore, we will instruct the Customs Service to continue to liquidate all entries of this merchandise exported on or after March 1, 1986, without regard to antidumping duties.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) § 353.22 of the Department regulations (19 CFR 353.22(c)(5)).

Dated: October 31, 1991.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import Administration.

[FR Doc. 91-26950 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-DS-M

[A-588-806]

### Electrolytic Manganese Dioxide From Japan; Preliminary Scope Ruling

**AGENCY:** International Trade Administration/Import Administration; Department of Commerce.

**ACTION:** Preliminary scope ruling.

**SUMMARY:** On July 7, 1989, the Department of Commerce (the Department) received a request from Sumitomo Corporation of America (SCOA) to clarify the scope of the outstanding antidumping duty order on electrolytic manganese dioxide (EMD) from Japan by ruling that high-grade chemical manganese dioxide (CMD-U) is outside the scope of the order.

By letter of July 17, 1989, the Department initiated a scope inquiry and invited interested parties to comment on SCOA's request. Having reviewed the comments received, we preliminarily determine that the merchandise in question is a later-developed product within the scope of the order. We invite interested parties to comment on this preliminary determination within 30 days of its publication. In accordance with section 781(e) of the Tariff Act of 1930, as amended, we have notified the International Trade Commission (ITC) of our proposed inclusion.

**EFFECTIVE DATE:** November 7, 1991.

**FOR FURTHER INFORMATION CONTACT:** Melissa Skinner or Carlo Cavagna, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-4851.

#### SUPPLEMENTARY INFORMATION:

##### Background

On May 31, 1988, Kerr-McGee Chemical Corporation (KMCC) and Chemetals, Inc. (Chemetals), filed a petition alleging that imports of electrolytic manganese dioxide (EMD) from Japan were being, or were likely to be, sold in the United States at less than fair value. Pursuant to their petition, the Department initiated its investigation on June 27, 1988. Initiation of Antidumping Duty Investigation: Electrolytic Manganese Dioxide From Japan, 53 FR 24116 (June 27, 1988). The final results of this investigation were published on March 2, 1989. Final Determination of Sales at Less Than Fair Value: Electrolytic Manganese Dioxide From Japan, 54 FR 8778 (March 2, 1989). The Department issued the antidumping duty order on April 17, 1989. Antidumping Duty Order: Electrolytic Manganese Dioxide From Japan, 54 FR 15244 (April 17, 1989).

On July 7, 1989, SCOA requested a ruling that CMD-U, which is manufactured by Chuo Denki Kogyo Co., Ltd. (Chuo Denki), is outside the scope of the antidumping duty order issued on EMD from Japan. Specifically, SCOA argued that only EMD is subject to the order and that EMD and CMD are not like products.

On July 17, 1989, we invited interested parties to comment on SCOA's request. We received comments from Petitioners, KMCC and Chemetals, arguing that CMD-U is a later-developed product that, based on an analysis of the criteria specified in 19 U.S.C. 1677j(d), is within the scope of the order. We received rebuttal comments from SCOA and Chuo Denki arguing that CMD-U is not a later-developed product and that all grades of CMD should be determined to be outside the scope of the antidumping order on EMD because CMD was excluded from the original investigation. By letter of June 5, 1990, Petitioners suggested that the later-developed product issue must be decided before ruling on SCOA's exclusion request.

By letter of October 22, 1990, the Department notified interested parties that "(a)ll comments in connection with this scope inquiry must be filed with the Department no later than November 2, 1990."

We received comments from KMCC and Chemetals and SCOA and Chuo Denki on or before November 2, 1990. Parties also continued to submit comments after the deadline date. Any comments received after November 2, 1990, were not considered to be filed in a timely manner, and, therefore, were not relied upon by the Department.

##### Criteria

For purposes of determining whether the merchandise in question is within the scope of the antidumping duty order on electrolytic manganese dioxide from Japan, we referred to section 353.29 of the Department's regulations on antidumping scope determinations. 19 CFR 353.29 (1990).

On matters concerning the scope of an antidumping duty order we first look to whether the descriptions of the product contained in the petition, the initial investigation, and the Department's and International Trade Commission's (ITC) determinations are dispositive. In this case, KMCC and Chemetals allege that CMD-U is a later-developed product. Section 353.29(h) of the regulations governs later-developed product scope determinations. Section 353.29(h) provides:

(1) In general. For purposes of determining whether a product developed after an



antidumping investigation is initiated (hereafter in this paragraph referred to as the "later-developed merchandise") is within the scope of an order, the Secretary will consider whether:

(i) The later-developed product has the same general physical characteristics as the merchandise with respect to which the order was originally issued (hereafter in this paragraph referred to as the "earlier merchandise");

(ii) The expectations of the ultimate purchasers of the later-developed product are the same as for the earlier merchandise;

(iii) The ultimate use of the earlier merchandise and the later-developed product are the same;

(iv) The later-developed product is sold through the same channels of trade as the earlier merchandise; and

(v) The later-developed product is advertised and displayed in a manner similar to the earlier merchandise.

With respect to later-developed products which incorporate a significant technological advance or significant alteration of an earlier product, § 353.29(d)(7)(iii) directs the Department to notify the ITC in writing of any proposed inclusion within the scope of the order and to consider any advice thereby provided by the ITC prior to issuing a final ruling. See also, section 781(d) of the Tariff Act of 1930, as amended, 19 U.S.C. 1677j(d) (the Act).

Furthermore, § 353.29(h)(2) states that the Department may not exclude later-developed products from an order merely because the products:

(i) Are classified under a tariff classification other than that identified in the petition or the Secretary's prior notices during the proceeding; or

(ii) Permit the purchaser to perform additional functions, unless such additional functions constitute the primary use of the products and the cost of the additional functions constitute more than a significant portion of the total cost of production of the products.

#### 19 U.S.C. 1677j(d)(2) and 19 CFR 353.29(h)(2).

In the instant case, the Department determined that CMD-U is appropriately considered a later-developed product within the meaning of 19 U.S.C. 1677j(d). Therefore, the Department applied the criteria in § 353.29(h) in making its determination whether CMD-U is included within the scope of the antidumping duty order on EMD from Japan.

Documents from the underlying proceeding deemed relevant by the Department to the scope of the outstanding order were made a part of the record in the instant scope review. In completing its analysis, the Department considered any written arguments that interested parties

submitted within the specified time limits. Documents that were not presented to the Department or placed by it on the record do not constitute part of the administrative record attendant to this scope proceeding.

#### Arguments

##### *Petitioners*

KMCC alleged that the CMD-U produced by Chuo Denki is a later-developed product (within the meaning of section 781(d) of the Act) and should be included within the scope of the antidumping duty order on EMD from Japan. Submissions of September 28, 1989, February 15, 1990, the February 21, 1990. Petitioners suggested that the appropriate first step is to notify the ITC that we propose to include CMD-U within the scope of the order, thereby providing the ITC an opportunity to comment on whether the proposed inclusion of the later-developed CMD-U from Japan raises important injury issues. Submission of June 5, 1990.

Petitioners suggested that "for the purpose of applying 19 U.S.C. section 1677j, 'later-developed' means later commercial development, which is the only sense of later-development that is consistent with the tests specified by the statute" and that SCOA's "own submission shows that CMD-U did not reach commercial development until sometime after the May 31, 1988 filing of the petition and initiation of the antidumping investigation with respect to EMD from Japan." Submission of June 5, 1990 at 9. Petitioners rebutted SCOA and Chuo Denki's argument that because CMD-U was patented before the investigation, it should not be considered later-developed. Petitioners stated that using "the date that a process is patented as the date a product of that process is 'developed' is not workable. Submission of November 2, 1990 at 5. In support, Petitioners argued:

Many such products are never commercialized, that is, they never are successfully developed as products in trade. Many products that are ultimately developed never reach the market (and the attention of competitors) until long after the date of the patent application. It would be unreasonable to require petitioners to take account in their petitions of products they have never seen in the market and whose characteristics and competitive effect are unknown.

*Id.* at 5. In short, Petitioners argued that "(a) product is not 'developed' until (the) process of trial and error, experimentation and testing of the result, has been completed." *Id.* at 7.

In support of its position that CMD-U was still being developed at the time of the investigation, Petitioners cited an

undated news release which reported that Chuo Denki would not commence production of CMD-U until October 1990, and that feasibility studies were still being conducted at a pilot plant in 1988. Additionally, citing a March 7, 1988, news release from Nikkei Sangyo Shimbun, Petitioners stated that the first sample shipment of CMD-U from Chuo Denki to Toshiba Battery only occurred sometime after March 7, 1988. Noting that the antidumping petition with respect to EMD from Japan was filed on May 31, 1988 and that the Department initiated its less-than-fair-value sales investigation on June 27, 1988, Petitioners argued that "because the development of CMD-U did not occur until after the initiation of the EMD proceeding, Chuo Denki's CMD-U is 'later-developed merchandise.'" Submission of February 15, 1990 at 3.

In response to SCOA and Chuo Denki's April 16, 1990 submission, Petitioners argued that "(n)o statement in the petition or the USITC staff report or any determination of the ITA or USITC precludes a finding that CMD-U is later-developed merchandise covered by the antidumping duty order." Submission of June 5, 1990 at 5. They stated that the distinction drawn (in the petition) between EMD and CMD was "based on the properties of merchandise known and commercially available at the time of the filing." *Id.* at 5. Furthermore, the CMD excluded from the petition was "distinctly different from EMD in physical and performance characteristics and was not used then or now in primary consumer batteries in the United States, nor was it then or is it now being marketed to producers of such batteries." *Id.* at 5 and 6. Petitioners added that "(u)nlike the Belgian CMD (referred to in the petition), CMD-U is not only physically extremely similar to EMD in crystalline structure, surface area, absorption and density, purity, and discharge performance, but it also is being marketed in the U.S. exclusively to the U.S. manufacturers of primary consumer batteries." *Id.* at 6.

Petitioners argued that the "USITC staff report's observation that CMD was not within the scope of the investigations merely reflected its understanding of the investigation's scope as received from the Commerce Department \* \* \*. There is no indication in the staff report that the Commission or the staff applied a 'like product' analysis to the reported potential product." *Id.* at 7.

Petitioners asserted that the "distinction (in the petition between EMD and CMD) was not based on



methods of manufacture and did not and could not refer to manganese dioxide products not then commercially available. The evidence before the ITA does not support a claim that CMD-U is the same product as the CMD to which the petition referred, even though it may be manufactured by chemical precipitation." *Id.* at 8. In their November 2, 1990 submission, Petitioners repeated the argument that the CMD excluded from the petition and determination was "a different product with different physical characteristics and uses than either EMD or, now, CMD-U." November 2, 1990, appendix 1 ("Affidavit of Richard F. Wohletz") at 3.

In any case, Petitioners argued that because CMD-U is later-developed, the Department should not apply the standards in 19 CFR 353.29(i) which instruct the Department to look first to "the descriptions of the merchandise contained in the petition, the initial investigation, and the determinations of the Secretary and the Commission." Were the Department to apply the standards in section (i), it would be "contrary to the regulations" and would "limit investigation of what CMD-U in fact is and how it will compete." Submission of November 2, 1990, at 3. Rather, Petitioners stated that, in accordance with its regulations, the Department must apply the standards in 19 CFR 353.29(h), governing later-developed product determinations.

Petitioners argued that Chuo Denki's CMD-U meets the five part test outlined in 19 CFR 353.29(h) (see also 19 U.S.C. 1677j(d)) that the Department must use for the purpose of determining whether later-developed merchandise is within the scope of an outstanding order. Submission of February 15, 1990 and February 21, 1990. Petitioners concluded that CMD-U is a later-developed product within the meaning of the Act, and that comparison of CMD-U and EMD using the five factors specified in section 781(d)(1) of the Act indicates that CMD-U is to be covered by the EMD order. *Id.* at 10.

#### Respondents

By letter of April 16, 1990, SCOA and Chuo Denki opposed the request of KMCC and Chemetals for the initiation of an anticircumvention investigation and requested a ruling that CMD (including all grades of CMD) is outside the scope of the antidumping duty order against electrolytic manganese dioxide (EMD) from Japan. SCOA and Chuo Denki argued that "on the basis of the EMD antidumping order alone, without further inquiry, the Department should issue a ruling that CMD is outside the scope of the order." Submission of April

16, 1990 at 2. SCOA and Chuo Denki continued by saying that "(b)ecause all CMD is outside the scope of the order, it is unnecessary for the Department to even address Petitioners' later-developed merchandise arguments."

Submission of April 16, 1990 at 7. SCOA and Chuo Denki stated that if the Department pursues its analysis, it becomes even more clear that CMD-U is outside the scope of the order. Specifically, they argued that because CMD-U is a grade of CMD—not EMD, that "even if CMD-U were developed after initiation of the investigation, which it was not, the later-developed merchandise provision would be inapplicable." *Id.* at 8.

In support of their allegation that "Petitioners are attempting to include within the antidumping duty order CMD that they specifically requested the Department and (the ITC) to exclude," SCOA and Chuo Denki cited the petition for the imposition of antidumping duties in the matter of electrolytic manganese dioxide (EMD) from Japan, Ireland and Greece. In the petition, "Petitioners explicitly stated that CMD and EMD were not like products." Submission of April 16, 1990 at 3. SCOA and Chuo Denki also cited the March 6, 1989 pre-hearing brief of Chemetals and KMCC, in which the petitioners argued in front of the ITC that "NMD (natural manganese dioxide) and CMD are not like products and are not within the scope of these investigations." *Id.* at 5.

To support their claim that CMD-U was not included in the antidumping duty order on EMD, SCOA and Chuo Denki argued that all significant technological developments in CMD-U occurred before the investigation was initiated on June 27, 1988:

When significant technological advances occurred (in CMD), Chuo Denki applied for a new patent. The first patent dates back to April 16, 1984 \* \* \* Chuo Denki applied for the last of nine patents on June 25, 1986, two whole years before the Department initiated the antidumping investigation of EMD from Japan.

Submission of August 13, 1990 at 4. See also Submission of April 16, at appendix 5.

To show that CMD-U was developed by the time of the petition, SCOA and Chuo Denki also cited many articles publicizing the development of CMD-U, most of which were published before June 1988. Submission of April 16, 1990 at 12-15. Moreover, SCOA and Chuo Denki contended that Petitioners misrepresented what is meant by "later-developed":

In the face of \* \* \* overwhelming evidence that CMD-U is not "later-developed

merchandise," Petitioners assert that "later-developed" means "later commercial development." \* \* \* The inclusion of the word "commercial" is an attempt by Petitioners to read words into the statute. Nowhere in the statute regulations or legislative history is there a reference to "commercial production."

Submission of August 13, 1990 at 5.

The time lag between the development of CMD-U, which occurred prior to June 1988, and the commercialization of CMD-U, they argued, was caused by the fact that the testing of a newly developed product usually takes several years. Submission of October 4, 1990 at 2. Thus, "it would make no sense for the Department of equate development with commercialization" (*id.* at 2), because "development necessarily precedes commercialization." Submission of August 13, 1990 at 5.

SCOA and Chuo Denki argued that because CMD-U already existed at the time of the petition and because the antidumping duty order nevertheless specifically covered only EMD, it would be improper to consider CMD-U a later-developed product and to include it retroactively within the scope of the order. They suggested that "Petitioners now try to argue that the antidumping duty order should include one particular grade of CMD (known as CMD-U or CMD-2) and exclude other grades of CMD." Submission of April 16, 1990 at 5. Citing USITC Pub. No. 2177 at A-4, they stated that "[t]he ITC specifically considered whether CMD-U manufactured by Chuo Denki was a like product and found that it was not." *Id.* at 6. SCOA and Chuo Denki therefore argued that "[s]ince CMD is outside the scope of the order and CMD-U is a grade of CMD, CMD-U falls outside the scope of the order." *Id.* at 7.

#### Analysis

In determining whether CMD-U is appropriately considered a later-developed product under 19 U.S.C. 1677j(d), we evaluated the arguments raised by interested parties in light of the language of the statute, regulations, and the applicable legislative history. We conclude that if CMD-U was developed after the initial investigation, the Department must analyze CMD-U based on the criteria contained in § 353.29(h) of the Department's regulations, which governs later-developed product scope determinations. A product developed after the petition and investigation cannot have been specifically excluded from the scope of the original investigation. Accordingly, if CMD-U is later-developed, the descriptions of the



merchandise contained in the petition, the initial investigation, and the determinations of the Secretary and the Commission cannot be dispositive. However, if a product is developed before an antidumping case is initiated, the later-developed product provision is clearly inapplicable. See 19 U.S.C. 1677j(d)(1); and H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. (1988), reprinted in 134 Cong. Rec. H2031, H2035 (daily ed. April 20, 1988) ("The Senate amendment is designed to 'address the application of outstanding antidumping and countervailing duty orders to merchandise that is essentially the same as merchandise subject to an order but was developed after the original investigation was initiated' ". Therefore, in order to analyze CMD-U under the proper section of the regulations, the Department must first determine when CMD-U was developed.

Because Petitioners allege that CMD-U is a later-developed product not specifically considered in the investigation, we first examined the petition and the determinations of the Department and the ITC to see if they provide an indication whether CMD-U was developed at the time.

#### Petition:

The product covered by this petition is electrolytic manganese dioxide (EMD), an intermediate product used in the production of dry cell batteries. EMD is manganese dioxide ( $MnO_2$ ) that has been refined in the electrolysis process. . . . The end-users of EMD are battery companies.

(Emphasis added). Petition at 13 and 14 (May 31, 1988).

Two products related to, but different from, EMD are natural manganese dioxide (NMD) and chemical manganese dioxide (CMD). NMD is naturally occurring, battery-active manganese dioxide. CMD is chemically precipitated, battery-active manganese dioxide. Neither NMD nor CMD is used to any significant extent in the manufacture of primary consumer batteries in the United States and neither is produced in the United States.

(Emphasis added). *Id.* at 14 and 15.

CMD was developed in the mid-1950's by the Manganese Chemical Corporation. With the exception of certain very limited and unique applications where EMD has not found acceptance . . . CMD is not used in battery production in the United States . . . The properties of CMD differ from EMD in four major respects: Surface area, electrolytic absorption, density and morphology. The surface area of most CMD is nearly twice that of EMD, which causes its electrolytic absorption to be considerably higher. The higher porosity is also linked to the lower apparent density of CMD particles as compared with EMD. CMD particles also typically are more rounded in appearance than EMD particles. As a result, CMD generally exhibits lower discharge rates than EMD.

(Emphasis added). *Id.* at footnote 6.

#### Scope of the Investigation:

The product covered by this investigation is electrolytic manganese dioxide from Japan . . . EMD is manganese dioxide [ $MnO_2$ ] that has been refined in an electrolysis process. The subject merchandise is an intermediate product used in the production of dry cell batteries.

(Emphasis added). Final Determination of Sales of Less Than Fair Value: Electrolytic Manganese Dioxide From Japan, 54 FR 8778 (March 2, 1989). See also, 53 FR 24116, June 27, 1988 (Initiation of Antidumping Duty Investigation), 53 FR 45796, November 14, 1988 (Preliminary Determination of Sales at Less Than Fair Value), and 54 FR 15244, April 17, 1989 (Antidumping Duty Order).

#### ITC:

In addition to EMD, there are two other types of manganese dioxide, both of which are also used in dry-cell batteries: natural manganese dioxide (NMD) and chemical manganese dioxide (CMD) . . . CMD is chemically precipitated, battery-active manganese dioxide. It is generally produced . . . The properties of CMD differ from EMD in three major respects: Surface area, electrolytic absorption, and density. As a result, CMD generally exhibits lower discharge rates than does EMD. Chuo Denki Kogyo Co., a Sumitomo-group company in Japan, has indicated that it hopes to commercialize by about 1990 a chemical manganese dioxide "comparable with, or superior to, electrolytic type in quality." . . . CMD is not within the scope of these investigations.

(Footnote omitted, emphasis added). USITC Pub. No. 2177 at A-3, A-4 (April 1989).

The petition and the determinations of the Department and the ITC excluded CMD from the scope of the investigations. However, our review of the language of the petition and determinations also shows that CMD-U, the high grade CMD with EMD-like properties, was not specifically considered. Based on an undated news release, Petitioners stated that the original manufacturing methods used by Chuo Denki (in 1986) produced a CMD that was suitable for certain battery applications (those involving heavy load discharge, such as radio-cassette recorders and flashlights), but not for others (those involving light load discharge, such as radios and watches). Submission of February 21, 1990 at 2. Citing the Petition (at 15), SCOA and Chuo Denki noted that CMD was not used "to any significant extent in the manufacture of primary consumer batteries." Submission of April 16, 1990 at appendix 1. The language cited above suggests that CMD was not included

mainly because, at the time, it was not used in the production of consumer batteries as a result of differences in physical characteristics between the EMD and CMD available when the petition was filed. The investigation specifically referenced only EMD because only EMD was suitable for the production of consumer batteries.

CMD-U is a type of chemically precipitated manganese dioxide that can indeed be used in the production of consumer batteries. SCOA and Chuo Denki concede this point: " . . . EMD and CMD-U have the same ultimate use . . . " Submission of April 16, 1990, appendix 1 at 4. As a result, we disagree with SCOA and Chuo Denki's assertion that because CMD was excluded from the original investigation, all grades of CMD must forever be excluded. The Department and the ITC did not consider and were not asked to consider CMD-U in their investigations. Moreover, the determinations of the Department and the ITC do not conclusively establish whether CMD-U was developed at the time of the initial investigation. Although SCOA and Chuo Denki argue that the ITC specifically considered the issue of whether or not CMD-U manufactured by Chuo Denki was a product like EMD and found that it was not, we do not think that this is a correct characterization of the ITC report. All the ITC report states is that development of CMD-U was still in progress at the time of the investigation. Specifically, the only mention the ITC report makes of CMD-U is that: "Chuo Denki Kogyo Co., a Sumitomo-group company in Japan, has indicated that it hopes to commercialize by about 1990 a chemical manganese dioxide 'comparable with, or superior to, electrolytic type in quality.' " USITC Pub. No. 2177 at A-3, A-4 (April 1989).

The evidence on the record in this proceeding supports the conclusion that CMD-U was in development at the time of the original investigation and was not fully tested or readied for commercial production. According to the Chemical Industry Daily Report (July 27, 1989), Chuo Denki did not announce development of CMD-U until July 1989: "Chuo Denki Kogyo announced on the 26th that they have developed a new type of CMD (Registered Name: CMD-U) with performances in batteries same as EMD, and that they plan to construct a plant to start a mass production." SCOA and Chuo Denki submission of April 16, 1990 at appendix 8. Clearly, a product whose development was not announced until 1989 could not have been developed at the time of the initial investigation, in mid-1988. A Bureau of



Mines report also indicated that work on production equipment was only just beginning in mid-1989 and that CMD-U would not appear on the market for the first time until 1990:

In Japan, Chuo Denki Kogyo Company announced that it was investing about \$19 million for construction of a new plant for production of high-grade chemical manganese dioxide (CMD-U) \* \* \*. Annual capacity for 11,000 tons of manganese chemicals is projected to be operational by April 1990 and for 6,600 tons of CMD-U by October 1990. The CMD-U is expected to compete with electrolytic manganese dioxide in battery applications.

"Manganese in July 1989," U.S. Bureau of Mines, Mineral Industry Surveys (Sept. 11, 1989); reproduced in KMCC submission of September 28, 1989 at Appendix B.

We agree with Petitioners that development usually requires a long process of "Trial and error, experimentation and testing." KMCC Submission of November 2, 1990 at 5. Although SCOA and Chuo Denki show that CMD-U was patented before the investigation, a patent does not necessarily indicate that a product is "developed" for purposes of 19 U.S.C. 1677(d)(1). In this case, feasibility studies of CMD-U were still being conducted in 1988. KMCC and Chemetals submission of February 15 at appendix 1. SCOA and Chuo Denki also argue that the sample shipments of CMD-U in 1988 indicate that CMD-U was developed. However, we agree with Petitioners that giving samples of a new product to battery producers, in order to allow them to test the samples and provide feedback, is part of the development process. The evaluation test results of the CMD-U samples were not expected to be available to Chuo Denki until August 1988 at the earliest, according to a March 7, 1988 news release from Nikkei Sangyo Shimbun:

Chuo Denki Kogyo is about to make a sample shipment of [CMD-U] to Toshiba Battery \* \* \*. Trial manufacturing facilities \* \* \* has been completed and substantiating test setup is now ready \* \* \*. Evaluation test results are to be compiled by around August this year \* \* \*. The plan is to compile by around the end of August this year, the results of the samples that had been shipped to the battery makers.

KMCC and Chemetals submission of February 15 at appendix 2.

Therefore, we find that the issuance of patents and product samples is not sufficient to show that a product is "developed" for purposes of 19 U.S.C. 1677(d)(1).

Based on the foregoing, we determine that CMD-U was developed after the initiation of the original investigation.

Therefore, we have applied the criteria set forth in § 353.29(h) of the Department's regulations governing later-developed product determinations to determine whether CMD-U is within the scope of the order.

#### (1) Physical Characteristics

SCOA and Chuo Denki did not rebut Petitioners' assessment of the similarities between the physical characteristics of CMD-U and EMD. They simply argued that CMD (including CMD-U) is produced through a chemical reaction process whereas EMD is produced through an electrolysis process. SCOA and Chuo Denki submission of April 16, 1990 at appendix 1. Petitioners asserted that CMD-U is essentially the same as EMD with respect to its crystalline structure, which is a fundamental characteristic of the product contributing to its superior performance, marketability, and suitability for use in primary consumer batteries. In addition to having the same chemical and crystalline structure, both are sold in the same form, a dry, black powder, and the particle size and shape of the two products are very similar. Like EMD, CMD-U is available in both an alkaline and a zinc chloride grade. KMCC and Chemetals submission of February 15 and 21, 1990.

While the production process is a factor to be considered, it is not necessarily dispositive of a product's physical characteristics, nor is it determinative of whether a product is considered within the scope of an order. For example, in Erasable Programmable Read Only Memories (EPROMs) from Japan: Final Determination of Sales at Less than Fair Value, 51 FR 39680 (October 30, 1986), the Department found that, with respect to EPROMs produced using different process technologies (Complementary and N-Channel Metal Oxide Semiconductor processes), "while there are differences in speed, complexity and the cost of the two devices, they are fundamentally similar in their design and purpose such as to make them substantially interchangeable and within the same class or kind of merchandise." *Id.* at 39685. CMD-U and EMD are analogous to EPROMs in this respect. Therefore, even though somewhat different production processes may be employed, EMD and CMD-U are similar in their general physical characteristics.

#### (2) Expectations of the Ultimate Purchasers

Petitioners alleged that Chuo Denki has deliberately set about to create the same customer expectations for CMD-U as exist for EMD. In support of this

allegation, Petitioners cited comments appearing in a press release ("performance is equal to that of electrolytic manganese dioxide"), a news release ("the product will be used in dry batteries"), a Bureau of Mines report ("CMD-U is expected to compete with electrolytic manganese dioxide in battery applications"), and a CMD-U product brochure "designed to demonstrate the similarities between EMD and CMD-U" and providing "technical details concerning the optimal construction of a dry cell battery using CMD-U." Petitioners argued that this illustrates Chuo Denki's intention to convince battery manufacturers that CMD-U is interchangeable with EMD, *i.e.*, that customers can expect the same performance from CMD-U as EMD in their batteries. KMCC and Chemetals submission of February 15 and 21, 1990 at 6 and 7.

SCOA and Chuo Denki did not rebut Petitioners' allegations. Instead, they asserted that grades of CMD other than CMD-U are not used to any significant extent in the manufacture of primary consumer batteries. SCOA and Chuo Denki submission of April 16, 1991 at appendix 1. This argument, however, is not relevant in this scope inquiry given that the subject is CMD-U, not CMD. Further, SCOA and Chuo Denki assert that the expectations of ultimate users of EMD and CMD-U differ because users probably will expect to pay less for CMD-U than for EMD since CMD-U is cheaper to produce. SCOA and Chuo Denki submission of April 16, 1990 at appendix 1. However, the performance of CMD-U in batteries is similar or the same as EMD, and there is no evidence in the record establishing any significant price difference. Therefore, we find that the expectations of the ultimate purchasers of CMD-U and EMD are the same.

#### (3) Ultimate Use of the Product

Petitioners alleged that CMD-U is designed primarily for use in dry cell batteries, which is the primary end use of EMD. In support, Petitioners cited Chuo Denki's February 13, 1986 patent application, which referred to the need to solve problems (with conventional chemical production processes for CMD) to obtain low-cost, high-quality batteries. Additionally, Petitioners alleged that, in its March 7, 1988 news release, Chuo Denki made it clear that "its CMD-U was being developed for use in manufacturing dry batteries," and that "the market for CMD-U is to be developed at the expense of EMD through price competition." Petitioners



also alleged that the "technical data in Chuo Denki's CMD-U product brochure demonstrates that CMD-U is designed for use in dry cell batteries." *Id.* at 8.

SCOA and Chuo Denki acknowledged that "EMD and CMD-U have the same ultimate use" (SCOA and Chuo Denki submission of April 16, 1990, Appendix 1), which is the manufacture of primary consumer batteries. We agree with the parties on this point and conclude that the ultimate use of CMD-U is the same as that for EMD: to produce consumer batteries.

#### (4) Channels of Trade

Petitioners argued that EMD and CMD-U move in the same channels of trade because both are marketed by large Japanese trading companies located in the United States. KMCC and Chemetals submission of February 15 and 21, 1990 at 9. SCOA and Chuo Denki argued that EMD and CMD-U move in different channels of trade because CMD moves exclusively through import channels while EMD moves through domestic channels. SCOA and Chuo Denki submission of April 16, 1990 at appendix 1.

We find neither of these arguments persuasive. Rather, we relied upon the un rebutted allegations of petitioners. Specifically, petitioners alleged that SCOA and Chuo Denki are using the same sales approach for CMD-U that U.S. producers and other U.S. importers have used for EMD—sales directly to end users (U.S. battery manufacturers) through sales representatives. KMCC and Chemetals submission of February 15 and 21, 1990 at 9. We also note that the petition identified Sumitomo Corporation of America (one of the requesters in this proceeding) as having been "[t]he United States importer of EMD manufactured by JMC \* \* \*". Petition at 12, footnote 4, May 31, 1988. Therefore, we find that EMD and CMD-U move in the same channels of trade.

#### (5) Advertisement and Display

Petitioners stated the EMD is marketed through direct contacts instead of advertising, and that it believes that "Sumitomo is using the same sales approach [for CMD-U] that U.S. producers and foreign producers of EMD use." KMCC and Chemetals submission of November 2, 1990 at 10. Specifically, KMCC stated that "[t]he later developed product is likely to be advertised as EMD is advertised, through brochures, technical leaflets, and presentation materials given to the battery companies at sales/technical meetings." KMCC submission of September 28, 1989 at 7. Petitioners added that "Sumitomo has not disclosed

the details of its current marketing program in the United States." KMCC and Chemetals submission of November 2, 1990 at 10. However, Petitioners also argued that Chuo Denki has attempted to create the same customer expectations for CMD-U as exist for EMD (see above), an allegation which suggests that similarities in advertising exist.

Requesters did not address the fifth criterion governing late-developed product scope determinations. Therefore, we accept Petitioners' un rebutted arguments and determine that EMD and CMD-U are advertised and displayed in a similar manner.

#### Conclusion

CMD-U was not specifically included or excluded from the scope of the order because development of CMD-U was not yet complete at the time of the petition and investigation. Therefore, CMD-U is a "later-developed product." Because of the similarities between the physical characteristics, the expectations of the ultimate purchasers, the ultimate uses, the channels of trade, and the methods of advertisement and display, CMD-U is the same class or kind of merchandise as EMD, and, therefore, subject to the antidumping duty order on EMD from Japan. We invite interested parties to comment on this preliminary determination within 30 days of publication of this preliminary determination. See 19 CFR 353.29(d)(3).

#### ITC Notification

CMD-U was created through advances in a manufacturing process that enabled a chemical form of manganese dioxide to be used in dry cell batteries. At the time of the original investigation, the existing technology did not yield a product suitable for such use. Therefore, we determine that CMD-U incorporates a significant technological advancement or significant alteration of an earlier product. Accordingly, because we preliminarily determine that a certain later-developed product which incorporates a significant technological advance or significant alteration is within the same class or kind of merchandise as EMD, we have notified the ITC in accordance with section 781(e) of the Act.

The preliminary scope ruling is in accordance with section 781(d) of the Tariff Act. 19 U.S.C. 1677j(d).

Dated: October 29, 1991.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance,

[FR Doc. 91-26951 Filed 11-6-91; 8:45am]

BILLING CODE 3510-DS-M

#### Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

**AGENCY:** International Trade Administration/Import Administration Department of Commerce.

**ACTION:** Notice of opportunity to request administrative review of antidumping or countervailing duty order, finding, or suspended investigation.

**BACKGROUND:** Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party as defined in section 771(9) of the Tariff Act of 1930 may request, in accordance with § 353.22 or § 355.22 of the Commerce Regulations, that the Department of Commerce ("the Department") conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

**OPPORTUNITY TO REQUEST A REVIEW:** Not later than November 30, 1991, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in November for the following periods:

Antidumping duty proceedings	Period
Argentina: Barbed Wire and Barbless Fencing Wire (A-357-405).....	11/01/90-10/31/91
Argentina: Steel Wire Rod (A-357-007).....	11/01/90-10/31/91
Japan: Bicycle Speedometers (A-588-038).....	11/01/90-10/31/91
Japan: Light Scattering Instruments (A-588-813).....	07/10/90-10/31/91
Japan: Titanium Sponge (A-588-020).....	11/01/90-10/31/91
The Federal Republic of Germany: Drycleaning Machinery (A-428-037).....	11/01/90-10/31/91
The Republic of Singapore: Rectangular Pipes and Tubes (A-559-502).....	11/01/90-10/31/91
Suspension Agreements: Japan: Certain Small Motors (A-588-090).....	11/01/90-10/31/91
Singapore: Certain Refrigeration Compressors (C-559-001).....	04/01/90-03/31/91
Countervailing Duty Proceedings: Argentina: Certain Textiles and Textile Products (C-357-048).....	01/01/90-12/31/90
Argentina: Oil Country Tubular Goods (C-357-403).....	01/01/90-12/31/90
Peru: Deformed Steel Concrete Reinforcing Bar (C-333-502).....	01/01/90-12/31/90

In accordance with § 353.22(a) of the Commerce regulations, an interested



party may request in writing that the Secretary conduct an administrative review of specified individual producers or resellers covered by an order, if the requesting person states why the person desires the Secretary to review those particular producers or resellers. If the interested party intends for the Secretary to review sales of merchandise by a reseller (or a producer if that producer also resells merchandise from other suppliers) which was produced in more than one country of origin, and each country of origin is subject to a separate order, then the interested party must state specifically which reseller(s) and which countries of origin for each reseller the request is intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, room B-099, U.S. Department of Commerce, Washington, DC 20230. Further, in accordance with section 353.31 of the Commerce Regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the *Federal Register* a notice of "Initiation of Antidumping (Countervailing) Duty Administrative Review", for requests received by November 30, 1991.

If the Department does not receive by November 30, 1991 a request for review of entries covered by an order or finding listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute, but is published as a service to the international trading community.

Dated: October 31, 1991.

Joseph A. Spetrini,  
Deputy Assistant Secretary for Compliance.  
[FR Doc. 91-26949 Filed 11-6-91; 8:45 am]  
BILLING CODE 3510-DS-M

[C-333-502]

#### Deformed Steel Concrete Reinforcing Bar (Rebar) From Peru; Intent To Revoke Countervailing Duty Order

**AGENCY:** International Trade Administration/Import Administration, Department of Commerce.

**ACTION:** Notice of intent to revoke countervailing duty order.

**SUMMARY:** The Department of Commerce is notifying the public of its intent to revoke the countervailing duty order on rebar from Peru. Interested parties who object to this revocation must submit their comments in writing not later than November 30, 1991.

**EFFECTIVE DATE:** November 7, 1991.

**FOR FURTHER INFORMATION CONTACT:** Beth Chalecki or Maria MacKay, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-2786.

#### SUPPLEMENTARY INFORMATION:

##### Background

On November 27, 1985, the Department of Commerce ("the Department") published a countervailing duty order on rebar from Peru (50 FR 48819). The Department has not received a request to conduct an administrative review of the countervailing duty order on rebar from Peru for more than four consecutive annual anniversary months.

In accordance with 19 CFR 355.25(d)(iii), the Secretary of Commerce will conclude that an order is no longer of interest to interested parties and will revoke the order if no interested party objects to revocation or requests an administrative review by the last day of the fifth anniversary month. Accordingly, as required by § 355.25(d)(4) of the Department's regulations, we are notifying the public of our intent to revoke this order.

Seven copies of any such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, room B-099, U.S. Department of Commerce, Washington, DC 20230.

If interested parties do not request an administrative review or object to the Department's intent to revoke by November 30, 1991, we shall conclude that the order is no longer of interest to interested parties and shall proceed with the revocation.

This notice is in accordance with 19 CFR 355.25(d).

Dated: October 31, 1991.

Joseph A. Spetrini,  
Deputy Assistant Secretary for Compliance.  
[FR Doc. 91-26953 Filed 11-6-91; 8:45 am]  
BILLING CODE 3510-DS-M

[C-557-806]

#### Postponement of Preliminary Countervailing Duty Determination: Extruded Rubber Thread From Malaysia

**AGENCY:** Import Administration, International Trade Administration, Commerce.

**EFFECTIVE DATE:** November 7, 1991.

**FOR FURTHER INFORMATION CONTACT:** Vince Kane or Gary Bettger, Office of Countervailing Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, at (202) 377-2815 or 377-2239, respectively.

#### Postponement

On October 25, 1991, the North American Rubber Thread Company, petitioner in this investigation, requested that the Department postpone the preliminary determination in accordance with section 703(c)(1)(A) of the Tariff Act of 1930, as amended (the Act). Accordingly, we are postponing the date of the preliminary determination until not later than December 13, 1991.

This notice is published pursuant to section 703(c)(2) of the Act and 19 CFR 355.15(d).

Dated: November 4, 1991.

Marjorie Chorlins,  
Acting Assistant Secretary for Import Administration.  
[FR Doc. 91-26952 Filed 11-6-91; 8:45 am]  
BILLING CODE 3510-DS-M

#### Minority Business Development Agency

##### Business Development Center Applications: Tucson, AZ

**AGENCY:** Minority Business Development Agency, Commerce.

**ACTION:** Notice.

**SUMMARY:** In accordance with Executive Order 11625, the Minority Business Development Agency (MBDA) is soliciting competitive applications under its Minority Business Development Center (MBDC) Program to operate an MBDC for approximately a 3-year period, subject to Agency priorities, recipient performance, and the availability of funds. The cost of performance for the first budget period (12 months) is estimated at \$165,000 in Federal funds and a minimum of \$29,118 in non-Federal (cost sharing) contributions. Cost-Sharing



contributions may be in the form of cash contributions, client fees, in-kind contributions or combinations thereof. The period of performance will be from April 1, 1992 to March 31, 1993. The MBDC will operate in the Tucson, Arizona Geographic Service Area.

The award number for this MBDC will be 09-10-92006-01.

The funding instrument for the MBDC will be a cooperative agreement. Competition is open to individuals, non-profit and for-profit organizations, State and local governments, American Indian Tribes and educational institutions.

The MBDC program is designed to provide business development services to the minority business community for the establishment and operation of viable minority businesses. To this end, MBDA funds organizations that can identify and coordinate public and private sector resources on behalf of minority individuals and firms; offer a full range of management and technical assistance; and serve as a conduit of information and assistance regarding minority business.

Applications will be evaluated initially by regional staff on the following criteria: The experience and capabilities of the firm and its staff in addressing the needs of the business community in general and, specifically, the special needs of minority businesses, individuals and organizations (50 points); the resources available to the firm in providing business development services (10 points); the firm's approach (techniques and methodologies) to performing the work requirements included in the application (20 points); and the firm's estimated cost for providing such assistance (20 points). An application must receive at least 70% of the points assigned to any one evaluation criteria category to be considered programmatically acceptable and responsive. The selection of an application for further processing by MBDA will be made by the Director based on a determination of the application most likely to further the purpose of the MBDC program. The application will then be forwarded to the Department for final processing and approval, if appropriate. The Director will consider past performance of the applicant on previous Federal awards.

MBDCs shall be required to contribute at least 15% of the total project cost through non-Federal contributions. To assist them in this effort, MBDCs may charge client fees for management and technical assistance (M&TA) rendered. Based on a standard rate of \$50.00 per hour, MBDCs will charge client fees at 20% of the total cost for firms with gross sales of \$500,000 or less, and 35% of the

total cost for firms with gross sales of over \$500,000.

MBDCs performing satisfactorily may continue to operate after the initial competitive year for up to 2 additional budget periods. MBDCs with year-to-date "commendable" and "excellent" performance ratings may continue to be funded for up to 3 or 4 additional budget periods, respectively. Under no circumstances shall an MBDC be funded for more than 5 consecutive budget periods without competition. Periodic reviews culminating in year-to-date quantitative and qualitative evaluations will be conducted to determine if funding for the project should continue. Continued funding will be at the discretion of MBDA based on such factors as an MBDC's performance, the availability of funds and Agency priorities.

Awards under this program shall be subject to all Federal and Departmental regulations, policies, and procedures applicable to Federal assistance awards.

In accordance with OMB Circular A-129, "Managing Federal Credit Programs," applicants who have an outstanding account receivable with the Federal Government may not be considered for funding until these debts have been paid or arrangements satisfactory to the Department of Commerce are made to pay the debt.

Applicants are subject to Governmentwide Debarment and Suspension (Nonprocurement) requirements as stated in 15 CFR part 26.

The Departmental Grants Officer may terminate any grant/cooperative agreement in whole or in part at any time before the date of completion whenever it is determined that the MBDC has failed to comply with the conditions of the grant/cooperative agreement. Examples of some of the conditions which can cause termination are failure to meet cost-sharing requirements; unsatisfactory performance of MBDC work requirements; and reporting inaccurate or inflated claims of client assistance or client certification. Such inaccurate or inflated claims may be deemed illegal and punishable by law.

On November 18, 1988, Congress enacted the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, title V, subtitle D). The statute requires contractors and grantees of Federal agencies to certify that they will provide a drug-free workplace. Pursuant to these requirements, the applicable certification form must be completed by each applicant as a precondition for receiving Federal grant or cooperative agreement awards.

"Certification for Contracts, Grants, Loans, and Cooperative Agreements" and SF-LLL, the "Disclosure of Lobbying Activities" (if applicable) is required in accordance with section 319 of Public Law 101-121, which generally prohibits recipients of Federal contracts, grants, and loans from using Legislative Branches of the Federal Government in connection with a specific contract, grant or loan.

**CLOSING DATE:** The closing date for submitting an application is December 19, 1991. Applications must be postmarked on or before December 19, 1991.

Proposals will be reviewed by the Atlanta Regional Office. The mailing address for submission is: Atlanta Regional Office, Minority Business Development Agency, U.S. Department of Commerce, 401 West Peachtree Street NW., suite 1930, Atlanta, Georgia 30308-3516, 404/730-3300.

A pre-application conference to assist all interested applicants will be held at the following address and time: San Francisco Regional Office, Minority Business Development Agency, U.S. Department of Commerce, 221 Main Street, room 1280, San Francisco, California 94105. November 27, 1991 at 10 a.m.

**FOR FURTHER INFORMATION CONTACT:** Xavier Mena, Regional Director, San Francisco Regional Office at 415/744-3001.

**SUPPLEMENTARY INFORMATION:** Anticipated processing time of this award is 120 days. Executive Order 12372, "Intergovernmental Review of Federal Programs," is not applicable to this program. Questions concerning the preceding information, copies of application kits and applicable regulations can be obtained from the San Francisco Regional Office.

11.800 Minority Business Development (Catalog of Federal Domestic Assistance). November 1, 1991.

Xavier Mena,  
Regional Director,  
San Francisco Regional Office.  
[FR Doc. 91-26864 Filed 11-6-91; 8:45 am]  
BILLING CODE 3510-21-M

## National Institute of Standards and Technology

[Docket No. 910809-1209]

### Precision Measurement Grants

**AGENCY:** National Institute of Standards and Technology, Commerce.



**ACTION:** Announcing Continuation of the NIST Precision Measurement Grants Program.

Catalog of Federal Domestic Assistance  
Name and Number: Measurement and  
Engineering Research and Services; 11.609.

**SUMMARY:** The purpose of this notice is to inform potential applicants that the National Institute of Standards and Technology (NIST) is continuing a program of research grants, formally titled Precision Measurement Grants, to scientists in U.S. academic institutions for significant, primarily experimental research, in the field of precision measurement and fundamental constants. Applications are now being accepted for two new NIST Precision Measurement Grants to be awarded beginning October 1, 1992 (fiscal year 1993). Each grant is in the range of \$30,000-\$40,000 per year, renewable at NIST's option for up to two additional years.

**CLOSING DATE FOR APPLICATIONS:**

February 1, 1992, is the deadline for applying for the FY 93 awards.

**FOR FURTHER INFORMATION CONTACT:**

Dr. Barry N. Taylor, Chairman, NIST Precision Measurement Grants Committee, Bldg. 221, rm. B160, National Institute of Standards and Technology, Gaithersburg, MD 20899, (301) 975-4220.

**SUPPLEMENTARY INFORMATION:**

As authorized by section 2 of the Act of March 3, 1901 as amended (15 U.S.C. 272), the National Institute of Standards and Technology (NIST) conducts directly, and through grants and contracts, a basic and applied research program in the general area of precision measurement and the determination of fundamental constants of nature. As part of this research program, NIST has since 1970 awarded Precision Measurement Grants to scientists in U.S. academic institutions for significant, primarily experimental research in the field of precision measurement and fundamental constants.

NIST is now accepting applications for two new grants in the range of \$30,000-\$40,000 per year to be awarded for the Period October 1, 1992, through September 30, 1993 (fiscal year 1993). Each grant may be renewed for up to two additional years; however, future or continued funding will be at the discretion of NIST based on such factors as satisfactory performance and the availability of funds.

NIST sponsors these grants to encourage basic, measurement-related research in U.S. colleges and universities and to foster contacts between NIST scientists and those researchers in the U.S. academic

community who are actively engaged in such work. The Precision Measurement Grants are also intended to make it possible for workers in U.S. academic institutions to pursue new measurement ideas for which other sources of support may be difficult to find. The Precision Measurement Grants Program does not involve the payment of any matching funds from a state or local government and does not directly affect any state or local government. Accordingly, NIST has determined that Executive Order 12372 is not applicable to the Precision Measurement Grants Program. This notice does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

**Research Topics/Who May Apply**

There is considerable latitude in the kind of research projects which will be considered for support under the Precision Measurement Grants Program. The key requirement is that they generally support NIST work in the field of basic measurement science, for example:

Experimental and theoretical studies of fundamental physical phenomena to test the basic laws of physics or which may lead to improved or new fundamental measurement methods and standards.

The determination of important fundamental physical constants.

The development of new standards for physical measurement of the highest possible precision and accuracy.

In general, proposals for experimental research will be given preference over proposals for theoretical research because of the greater expense of experimental work. Proposals from workers at the assistant and associate professor level who have some record of accomplishment are especially encouraged in view of the comparative difficulty aspiring researchers have in obtaining funds.

Typical projects which have been funded through the NIST Precision Measurement Grants Program includes:

"Measurement of fundamental constants using three-level resonances in hydrogen," Carl E. Wieman, University of Michigan.

"Quantum limited measurement of a harmonic oscillator," William C. Oelfke, University of Central Florida.

"Fine-Structure constant determination using precision Stark spectroscopy," Michael G. Littman, Princeton University.

"Eötvös experiment-cryogenic version," D.F. Barlett, University of Colorado.

"A test of local Lorentz invariance using polarized  $^{21}\text{Ne}$  nuclei," T.E. Chupp, Harvard University.

"A new method to search for an electric dipole moment of the electron," L.R. Hunter, Amherst College.

"High precision timing of millisecond pulsars," D.R. Stinebring, Princeton University.

"Precision optical spectroscopy of positronium," S. Chu, Stanford University.

**Eligibility:** Universities, colleges, professional institutes and associations, nonprofit organizations, and state and local governments.

**Procedures**

To simplify the proposal writing and evaluation process, the following selection procedure will be used:

Candidates are requested to submit a preapplication proposal to NIST by February 1, 1992 using Standard Form 424 (Rev. 4-88) with a description of their proposed work of no more than five double spaced pages. Standard Form 424A (4-88) and 424B (4-88) are also required.

Three copies should be sent to Dr. Barry N. Taylor at the address shown above.

On the basis of this material, four to eight semi-finalist candidates will be selected by the NIST Precision Measurement Grants Committee and the Outside Advisory Committee to submit more detailed proposals. The same committees will evaluate the detailed proposals, and on the basis of their evaluation, the two grantees for fiscal year 1993 will be selected. The semi-finalists will be notified of their status by March 20, 1992, and will be requested to submit their full proposals to NIST by May 4, 1992. The successful grantees will be notified of their selection by August 15, 1992.

The criteria to be used in evaluating the preapplication proposals and full proposals include:

1. Importance of the proposed research to science—does it have the potential of answering some currently pressing question or of opening up a whole new area of activity?

2. The relationship of the proposed research to measurement science—is there a possibility that it will lead to a new or improved fundamental measurement method, basic measurement unit, or physical standard? (Or to a better understanding of important, but already existing, measurement methods, measurement units, or physical standards?)

3. The feasibility of the research—is it likely that significant progress can be



made in a three year time period with the funds and personnel available?

4. The past accomplishments of the applicant—is the quality of the research previously carried out by the prospective grantee such that there is a high probability that the proposed research will be successfully carried out?

Each of these factors are given equal weight in the selection process.

Technical Questions concerning the NIST Precision Measurement Grants Program may be directed to the above address or call Dr. Taylor on (301) 975-4220.

#### Paperwork Reduction Act

The standard forms 424, 424A and 424B referenced in this notice are subject to the Paperwork Reduction Act and are cleared under Office of Management and Budget (OMB) control numbers 0438-0043, 0348-0044 and 0348-0040.

#### Additional Requirements

All applicants must submit a certificate ensuring that employees of the applicant are prohibited from engaging in the unlawful manufacturing, distribution, dispensing, possession or use of a controlled substance at the work site, as required by the regulations implementing the Drug-Free Workplace of 1988, 15 CFR part 26, subpart F.

Applicants are subject to the Governmentwide Debarment and Suspension (Nonprocurement) requirements as stated in 15 CFR part 26.

Applicants are reminded that a false statement may be grounds for denial or termination of funds and grounds for possible punishment by fine or imprisonment. Any recipients/applicants who have an outstanding indebtedness to the Department of Commerce will not receive a new award until the debt is paid or arrangements satisfactory to the Department are made to pay the debt.

Applicants should be aware that all awards under this program shall be subject to all Federal and Departmental regulations, policies, and procedures applicable to financial assistance awards.

#### Administrative Information

Contact: Grants Office, Office of Acquisition and Assistance Division,

Building 301/rm. B143, National Institute of Standards and Technology, Gaithersburg, MD 20899, (301) 975-6328.

Dated: October 30, 1991.

John W. Lyons,

Director.

[FR Doc. 91-26851 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-13-M

#### National Oceanic and Atmospheric Administration

#### Endangered and Threatened Species, Sacramento River Winter-Run Chinook Salmon

**AGENCY:** National Marine Fisheries Service (NMFS), NOAA, Commerce.

**ACTION:** Notice of receipt of petition.

**SUMMARY:** NMFS has received a petition from the American Fisheries Society (California-Nevada Chapter) to reclassify the Sacramento River winter-run chinook salmon as endangered rather than threatened. NMFS has determined that the petition contains substantial information indicating that the petitioned action may be warranted, and will review the status of the species to determine if it should be reclassified under provisions of the Endangered Species Act. To ensure that the review is comprehensive, NMFS is soliciting information and data concerning the status of this species.

**DATES:** Information should be received by December 9, 1991.

**ADDRESSES:** E. Charles Fullerton, Director, Southwest Region, NMFS, 300 S. Ferry Street, Terminal Island, CA 90731.

**FOR FURTHER INFORMATION CONTACT:** James E. Lecky, NMFS, Southwest Region, (213) 514-6664 or Margaret Lorenz, NMFS, Office of Protected Resources (301) 427-2322.

#### SUPPLEMENTARY INFORMATION:

##### Background

After a review of the status of the Sacramento River winter-run chinook salmon, NMFS determined that it should be added to the list of Threatened and Endangered Species as threatened. The species was added to the list on an emergency basis in August 1989 and listed finally November 30, 1990 (55 FR 46515).

On June 5, 1991, NMFS received a petition from the California-Nevada Chapter of the American Fisheries Society requesting NMFS to reclassify this species from threatened to

endangered. The request was based on preliminary data that only 88 to 200 adults had returned to the Sacramento River to spawn in 1991.

Based on final estimates from the California Department of Fish and Game (CDFG), which placed the number of returning adult salmon at about 200, NMFS believes the petition contains substantial information indicating that reclassification may be warranted. Therefore, NMFS will conduct a new status review to determine if reclassification is warranted.

Counts since 1966 by CDFG at Red Bluff Diversion Dam show a persistent decline in run size from a 3-year average of about 84,000 fish from 1967 through 1969 to 2,000 from 1982 through 1984. In 1989, 550 adult fish returned, and in 1990, 441 returned.

#### Biological Information Solicited

To ensure that the review is complete and is based on the best available scientific data, NMFS is soliciting information concerning the status of the winter-run chinook salmon from any interested person. We request that data, information, and comments be accompanied by (1) supporting documentation such as maps, bibliographic reference, or reprints of pertinent publications and (2) the person's name, address, and any association, institution, or business that the person represents.

Dated: October 31, 1991.

William W. Fox, Jr.,

Assistant Administrator for Fisheries.

[FR Doc. 91-26820 Filed 11-6-91; 8:45 am]

BILLING CODE 3510-22-M

#### COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

#### Announcement of an Import Restraint Limit and Guaranteed Access Level for Certain Cotton Textile Products Produced or Manufactured in Guatemala

November 1, 1991.

**AGENCY:** Committee for the Implementation of Textile Agreements (CITA).

**ACTION:** Issuing a directive to the Commissioner of Customs establishing a limit and guaranteed access level for the new agreement year.

**EFFECTIVE DATE:** January 1, 1992.



**FOR FURTHER INFORMATION CONTACT:** Nicole Bivens Collinson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 566-5810. For information on embargoes and quota re-openings, call (202) 377-3715.

**SUPPLEMENTARY INFORMATION:**

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Memorandum of Understanding (MOU) dated November 9, 1989 between the Governments of the United States and Guatemala establishes an import limit and guaranteed access level (GAL) for cotton textile products in Categories 347/348 for the period beginning on January 1, 1992 and extending through December 31, 1992.

A description of the textile and apparel categories in terms of HTS numbers is available in the **CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States** (see **Federal Register** notice 55 FR 50756, published on December 10, 1990). Information regarding the 1992 **CORRELATION** will be published in the **Federal Register** at a later date.

Requirements for participation in the Special Access Program are available in **Federal Register** notice 51 FR 21208, published on June 11, 1986; 52 FR 26057, published on July 10, 1987; 54 FR 50425, published on December 6, 1989; and 55 FR 3079, published on January 30, 1990.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOU, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,  
*Acting Chairman, Committee for the Implementation of Textile Agreements.*

**Committee for the Implementation of Textile Agreements**  
November 1, 1991.

Commissioner of Customs,  
*Department of the Treasury, Washington, DC 20229.*

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on July 31, 1991; pursuant to the Memorandum of Understanding (MOU) dated November 9, 1989 between the Governments of the United

States and Guatemala; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 1, 1992, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton textile products in Categories 347/348, produced or manufactured in Guatemala and exported during the twelve-month period beginning on January 1, 1992 and extending through December 31, 1992, in excess of 904,498 dozen.

Imports charged to this category limit for the period January 1, 1991 through December 31, 1991 shall be charged against that level of restraint to the extent of any unfilled balance. In the event the limit established for that period has been exhausted by previous entries, such goods shall be subject to the level set forth in this directive.

The limit set forth above is subject to adjustment in the future pursuant to the provisions of the MOU dated November 9, 1989 between the Governments of the United States and Guatemala.

Additionally, pursuant to the November 9, 1989 MOU and the terms of the Special Access Program, as set forth in 51 FR 21208 (June 11, 1986), 52 FR 26057 (July 10, 1987) and 54 FR 50425 (December 6, 1989), effective on January 1, 1992, a guaranteed access level of 1,000,000 dozen is being established for properly certified textile products assembled in Guatemala from fabric formed and cut in the United States in Categories 347/348 which are re-exported to the United States from Guatemala during the period January 1, 1992 through December 31, 1992.

Any shipment for entry under the Special Access Program which is not accompanied by a valid and correct certification and Export Declaration in accordance with the provisions of the certification requirements established in the directive of January 24, 1990 shall be denied entry unless the Government of Guatemala authorizes the entry and any charges to the appropriate specific limit. Any shipment which is declared for entry under the Special Access Program but found not to qualify shall be denied entry into the United States.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,  
*Acting Chairman, Committee for the Implementation of Textile Agreements.*  
[FR Doc. 91-26944 Filed 11-6-91; 8:45 am]

**BILLING CODE 3510-DR-F**

**DEPARTMENT OF DEFENSE**

**GENERAL SERVICES  
ADMINISTRATION**

**NATIONAL AERONAUTICS AND  
SPACE ADMINISTRATION**

[FAR Case 91-53]

**OMB Clearance Request for Increase  
in Cost or Pricing Data Threshold**

**AGENCIES:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice; request for revision to OMB Control No. 9000-0013.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision to reduce the burden of a currently approved information collection concerning Increase in Cost or Pricing Data Threshold.

**DATES:** Comments should be submitted to OMB on or before December 9, 1991.

**ADDRESSES:** Send comments to Mr. Peter Weiss, FAR Desk Officer, OMB, room 3235, NEOB, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jeremy Olson, Office of Federal Acquisition Policy, (202) 501-3221.

**SUPPLEMENTARY INFORMATION:**

**A. Purpose**

The Truth In Negotiations Act requires the Government to obtain certified cost or pricing data under certain circumstances. The statutory threshold for submittal of certified cost or pricing data has been increased from \$100,000 to \$500,000 for the Department of Defense, the National Aeronautics and Space Administration and the Coast Guard. Accordingly, the FAR policies are being changed to match the statutory requirements.

**B. Annual Reporting Burden**

The annual reporting burden is estimated as follows: *Respondents*, 14,781; *responses per respondent*, 7; *total annual responses*, 103,467; *hours per response*, 4; and *total response burden hours*, 413,868.

**Obtaining Copies of Proposals**

Requester may obtain copies of the proposed or interim rule and the justification for the OMB request from General Services Administration, FAR Secretariat (VRS), room 4041, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No.



9000-0013, Increase in Cost of Pricing Data Threshold (FAR case 91-53).

Dated: October 25, 1991.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 91-26888 Filed 11-6-91; 8:45 am]

BILLING CODE 6820-34-M

## DEPARTMENT OF DEFENSE

### Public Information Collection Requirement Submitted to OMB for Review

#### ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

*Title, Applicable Form, and Applicable OMB Control Number:* Carrier Selection and Performance, DLA Form 1773, OMB Number 0704-0291.

*Type of Request:* Reinstatement.  
*Average Burden Hours/Minutes Per Response:* .33 hours.

*Response Per Respondent:* 1.25 (Average).

*Number of Respondents:* 2000.

*Annual Burden Hours:* 825.

*Annual Responses:* 2500.

*Needs and Uses:* The Defense Logistics Agency (DLA), Office of the Secretary of Defense will use the form to provide information to DOD contractors regarding the selection of carriers to transport DOD purchased material. Contractors will use the information to contract primary or alternate carriers and to report performance or service deficiencies by carriers to DLA regional area offices. DLA reports carrier performance to the Military Traffic Management Command as part of their Carrier Performance Program.

*Affected Public:* Businesses or other for-profit and small businesses or organizations.

*Frequency:* On occasion.

*Respondent's Obligation:* Voluntary.

*OMB Desk Officer:* Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, room 3235, New Executive Office Building, Washington, DC 20503.

*DOD Clearance Officer:* Mr. William P. Pearce.

Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, suite 1204, Arlington, VA 22202-4302.

Dated: November 1, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-26818 Filed 11-6-91; 8:45 am]

BILLING CODE 3810-01-M

## Office of the Secretary

### Finding of No Significant Impact (FONSI) Pentagon Reservation Master Plan

**AGENCY:** Real Estate and Facilities, WHS, DOD.

**ACTION:** Notice.

**SUMMARY:** The Pentagon Reservation Master Plan has a development plan that consists of four major elements:

1. Construction of a replacement Heating and Refrigeration Plant.
2. Construction of a 600,000 gross square foot below grade Logistics Support Extension at the Mall Terrace.
3. Site Development.
4. Renovation of the Pentagon.

An environmental assessment of the Pentagon Reservation Master Plan has been prepared in accordance with the National Environmental Policy Act and Council on Environmental Quality Regulations.

The Environmental Assessment shows that the proposed development will not have any significant adverse impacts on the human environment. Specifically, the impacts of a replacement Heating and Refrigeration Plant on air quality and the impacts of renovation and modifications to the Pentagon, which is listed on the National Register of Historic Places, will not pose any significant adverse effects.

Four alternatives were considered for the Heating and Refrigeration Plant:

1. Repair existing coal-burning facility and equipment.
2. Repair existing facilities and replace existing coal-burning equipment with new coal-burning equipment.
3. Construct a new oil-and-gas burning facility on the existing sites.
4. Construct a new oil-and-gas burning facility elsewhere on the Reservation.

Replacement of the Heating and Refrigeration Plant on the present site was determined to be the most satisfactory solution, because of the existing support infrastructure and the availability of cooling water from the Pentagon Lagoon. Early coordination with the Virginia Department of Air Pollution Control has been conducted. Air quality modeling indicates that the new Heating and Refrigeration Plant would not exceed National Ambient Air Quality Standards. A permit will be

secured with the Virginia Department of Air Pollution Control to specify the design and condition of operating the plant, and to ensure compliance with Federal and State regulations.

The implementation of avoidance measures or data recovery plans (for significant archaeological sites) and implementation of the Secretary of the Interior's Standards and Guidelines (for all historic building renovation) will result in no significant impacts to cultural resources. Early coordination with the Virginia State Historic Preservation Officer has been conducted. The Environmental Assessment has been independently evaluated by the Department of Defense and determined to adequately and accurately discuss the environmental issues and impacts of the proposed development plan. It provides sufficient evidence and analysis for determining that an environmental impact statement is not required.

Mr. D. Cooke, Director of Administration and Management, therefore concludes that development of the Pentagon Reservation Master Plan will create no significant direct or indirect adverse impacts on the human environment.

**DATES:** Information and public comment related to this Environmental Assessment must be forwarded no later than December 9, 1991.

#### FOR FURTHER INFORMATION CONTACT:

Mr. Paul Christolini, Deputy Director, OSD/WH/Real Estate and Facilities, room 3C345, Pentagon, Washington, DC 20301-1155, (703) 697-7241.

Dated: November 1, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-26819 Filed 11-6-91; 8:45 am]

BILLING CODE 3810-01-M

## Defense Science Board Task Force on Anti-Submarine Warfare; Meeting

**ACTION:** Cancellation of portion of meeting.

**SUMMARY:** The second day of the meeting of the Defense Science Board Task Force on Anti-Submarine Warfare scheduled for November 13-14, 1991, as published in the Federal Register (vol. 56, no. 207, page 55289, Friday, October 25, 1991, FR Doc. 91-25685) is cancelled. In all other respects the original notice remains unchanged.



Dated: November 4, 1991.

Linda M. Bynum,

Alternate OSD Federal Register Liaison  
Officer, Department of Defense.

[FR Doc. 91-26999 Filed 11-6-91; 8:45 am]

BILLING CODE 38\*0-01-M

## Department of the Army

### Draft Environmental Impact Statement for the Deposition of Dredged Materials Over 1,830 Acres of Diked Historic Bayland (Seasonal Marsh) Resulting in the Restoration/Creation of Full Tidal Marsh in Solano County, CA

**AGENCY:** San Francisco District, Corps of Engineers, Department of the Army.

**ACTION:** Notice of intent to prepare a draft environmental impact statement.

**SUMMARY:** The Levine-Fricke Restoration Corporation have applied for a Department of the Army (DA) permit for authorization to discharge dredged and fill material, and to work in navigable waters of the United States in association with the deposition of approximately 25 million cubic yards or dredged materials over 1830 acres of diked historic bayland (seasonal marsh) in Solano County, California. It is proposed that the activity would result in the restoration/creation of full tidal marsh. The permit application process, scoping process, and preparation of the Draft EIS will be conducted by the Regulatory Branch of the San Francisco District.

#### FOR FURTHER INFORMATION CONTACT:

Questions regarding the scoping process and the preparation of the draft EIS may be directed to Dr. Susan Ryan at the Corps of Engineers (Telephone (415) 744-3322, ext. 224). Questions regarding the processing of the permit application may be directed to Mr. Robert Smith at the Corps of Engineers (Telephone (415) 744-3037, ext. 237).

#### SUPPLEMENTARY INFORMATION:

##### 1. Proposed Action.

The Corps of Engineers (Corps) has received an application for a Department of the Army permit from the Levine-Fricke Restoration Corporation to deposit approximately 25 million cubic yards of dredged materials over 1830 acres of diked historic bayland (seasonal marsh) in Solano County, California. It is proposed that the activity would result in the restoration/creation of full tidal marsh. The applicants expect a reasonable return on their investment as a result of project implementation. The proposed project site is located at the eastern perimeter

of the Suisun Marsh near the confluence of the Sacramento and San Joaquin rivers, Solano County, California. Current land uses include agricultural activities over much of the site (cattle and sheep grazing), recreational activities in the northern portion of the site (pheasant hunting) and adjacent to the Montezuma Gates (fishing), and a dredged sand and oyster shell industrial processing facility. The permit application will be processed by the Regulatory Branch of the San Francisco District, Corps of Engineers, pursuant to the provisions of section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 403) and section 404 of the Clean Water Act. (33 U.S.C. 1344).

The purpose of the proposed project is to deposit approximately 25 million cubic yards of dredged materials over 1830 acres of diked historic bayland (seasonal marsh), resulting in the restoration/creation of full tidal marsh.

In accordance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*) the Corps has determined that the proposed action may have a significant impact on the quality of the human environment and therefore requires the preparation of an Environmental Impact Statement (EIS). A combined EIS/EIR (Environmental Impact Report) will be prepared with the Corps as the Federal lead agency and the County of Solano as the lead agency for the EIR.

##### 2. Alternatives

The project alternatives under consideration are:

*a. Proposed project.* The proposed project would allow for construction of sediment offloading facilities, sediment transfer pipelines, holding ponds, effluent discharge pipe, upland staging and storage areas, office, laboratory, interior levees, and levee breach structures. Project activities would also involve the offloading and transfer of sediments to fill locations by pipeline, followed by sediment dewatering. Wetlands restoration/creation activities would include channel construction, topographic contouring, and flooding. Temporary and permanent monitoring equipment would also be installed as a result of project implementation.

*b. No action plan.* Under this plan, which is equivalent to permit denial by the Corps, no action could be taken by the Levine-Fricke Restoration Corporation to deposit approximately 25 million cubic yards of dredged materials over 1830 acres of diked historic bayland (seasonal marsh). In addition, there would be no restoration/creation of full tidal marsh.

*c. Alternative Site(s) for Wetland Restoration*

*d. Ocean Disposal for Dredged Sediments*

*e. Alternative Sites for Dredged Material Disposal*

*f. Other project proposals that are identified as feasible during the public scoping process.*

##### 3. Scoping Process.

Pursuant to the National Environmental Policy Act, as amended, agency planning for federal or federally permitted projects must include a "scoping" process. Scoping primarily involves determining the scope of issues to be addressed, and identifying the significant issues for in-depth analysis in the draft EIS. The scoping process includes public participation to integrate information regarding public needs and concerns into the environmental document.

The Corps and the County will hold a public scoping meeting on November 20, 1991 at 7 pm at the Board of Supervisors Chambers, 2nd floor, Old Courthouse, 580 Texas Street, Fairfield, CA 94533. A formal presentation will precede the request for public comment. Representatives from the Corps of Engineers and the County will be available at this meeting to receive comments from the public regarding issues of concern that should be addressed in the environmental document.

Agencies and the public are also invited and encouraged to provide written comments in addition to, or in lieu of, oral comments at the scoping meeting. To be most helpful, the scoping comments should clearly describe specific environmental issues or topics which the commentator believes the document should address. Written statements should be mailed no later than December 4, 1991 to the District Engineer, U.S. Army Corps of Engineers, San Francisco District, 211 Main Street, San Francisco, California 94105.

*a. Significant issues.* The following issues have been identified as potentially significant and will be evaluated in the draft EIS:

- (1) Wetlands.
- (2) Water quality.
- (3) Water supply.
- (4) Endangered species.
- (5) Geologic conditions.
- (6) Air quality.
- (7) Agricultural activity.
- (8) Wildlife habitat.
- (9) Noise conditions.
- (10) Traffic and transportation.
- (11) Cultural resources.
- (12) Recreational opportunities.



**b. Environmental requirements.**

Environmental review and other consultation requirements applicable to the proposed action include:

- (1) National Environmental Policy Act, as amended.
- (2) Clean Water Act, as amended.
- (3) Clean Air Act, as amended.
- (4) National Historic Preservation Act, as amended.
- (5) Fish and Wildlife Coordination Act.
- (6) Endangered Species Act, as amended; and
- (7) California Environmental Quality Act.

4. Availability of EIS. The Draft EIS will be available for public review in October 1992.

John O. Raach, II,

Department of the Army, Liaison Officer with the Federal Register.

[FR Doc. 91-26813 Filed 11-6-91; 8:45 am]

BILLING CODE 3710-FS-M

**Notice of Intent To Prepare a Draft Environmental Impact Statement for the Proposed Aggregate Mining and Reclamation of Six Sites on the Russian River in Sonoma County, CA**

**AGENCY:** San Francisco District, Corps of Engineers, Department of the Army.

**ACTION:** Notice of intent to prepare a Draft Environmental Impact Statement.

**SUMMARY:** Syar Industries have applied for Department of the Army (DA) permit to discharge dredged and fill material and work in the navigable waters of the United States in association with the proposed aggregate mining and reclamation of six sites in the Russian River in Sonoma County, California. The permit application process, scoping process, and preparation of the Draft EIS will be the responsibility of the Regulatory Branch of the San Francisco District.

**FOR FURTHER INFORMATION CONTACT:** Questions regarding the scoping process, preparation of the Draft EIS, and processing of the permit application may be directed to Jennifer Vick at the Corps of Engineers (Telephone 415-744-3322, ext. 225).

**SUPPLEMENTARY INFORMATION:**

**1. Proposed Action**

The Corps of Engineers has received an application for a Department of the Army permit from Syar Industries to mine aggregate resources and reclaim the mined sites at six locations on the Russian River in Sonoma County, California. The project proponent maintains vested rights to extract aggregate at five of the six locations.

This Draft EIS will address the impacts of the reclamation proposals for the five vested sites as well as the mining and reclamation of the new site. This new site is located within the City of Healdsburg. The permit will be processed by the Regulatory Branch of the San Francisco District, Corps of Engineers pursuant to the provisions of section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 403) and section 404 of the Clean Water Act (33 U.S.C. 1344).

The purpose of the proposed project is to reclaim five vested aggregate mining sites on or adjacent to the Russian River as well as mine and reclaim a new, sixth, site in the City of Healdsburg. The aggregate from the new site would be used to meet demand identified in Sonoma County. The project proponent states that the reclamation of the sites would enhance fisheries habitat, increase erosion protection, and improve riparian habitat on the Russian River.

In accordance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), the Corps has determined that the proposed action may have a significant impact on the quality of the human environment and therefore requires the preparation of an Environmental Impact Statement. A combined Environmental Impact Report/Environmental Impact Statement (EIR/EIS) with the Corps as the Federal lead agency for the EIS and California State Mining and Geology Board, the City of Healdsburg, and the County of Sonoma as the CEQA lead agencies for the EIR.

**2. Alternatives**

The project alternatives under consideration are:

**a. Proposed project:** The proposed plan would allow for the removal of approximately 3.6 million tons of aggregate currently exploitable under the proponent's vested rights. In addition, 225,000 tons of aggregate would be removed from the new site. These sites include five instream locations covering a total of 98 acres and one 60-acre terrace location. All instream locations would be mined by skimming and channel excavation. The terrace would be mined by excavation. Instream reclamation would include revegetation of disturbed riparian habitat, regrading of access roads, channel diversion/realignment, and the construction of spur dikes. The terrace location would be reclaimed by the diversion of high flows from the Russian River through the pit and by refilling with fine sediments recovered during aggregate processing.

**b. No action alternative:** This alternative would entail no reclamation of the five vested sites. Also, no mining at the proposed new site in the City of Healdsburg would occur.

**c. No development alternative:** This alternative would include no mining or reclamation at any of the six sites to be discussed in the EIR/EIS.

- d. Gravel Bar Skimming Alternative
- e. Streamway or Terrace Skimming Alternative

**3. Scoping Process**

Pursuant to the National Environmental Policy Act, as amended, agency planning for federal or federally permitted projects must include a scoping process. Scoping primarily involves determining the scope of issues to be addressed and identifying significant issues for in-depth analysis in the draft EIS. The scoping process includes public participation to integrate information regarding public needs and concerns into the environmental document.

The Corps of Engineers, the California State Mining and Geology Board, and the City of Healdsburg will hold a public scoping meeting on December 17, 1991 at 7 pm at the Senior Center, 134 Matheson Street, Healdsburg, California 95448. Representatives from the Corps of Engineers, the California State Mining and Geology Board, the City of Healdsburg, and EIP Associates (the consultant preparing the EIR/EIS will be available at this meeting to receive comments from the public regarding issues of concern that should be addressed in the environmental document.

Agencies and the public are also invited and encouraged to provide written comments in addition to, or in lieu of, oral comments at the scoping meeting. These comments should specifically describe environmental issues or topics which the commentator believes the document should address. Written statements should be mailed no later than December 31, 1991 to the District Engineer, U.S. Army Corps of Engineers, San Francisco District, 211 Main Street, San Francisco, California, 94105 ATTN: Jennifer Vick.

**a. Significant issues**

The following issues have been identified as potentially significant and will be evaluated in the Draft EIR/EIS. However, the scope of analysis is not limited to these issues.

- (1) Geologic conditions
- (2) Water quality/supply
- (3) Erosion/sedimentation rates
- (4) Air quality



(5) Habitat for fish, other aquatic organisms, and wildlife

(6) Pool and riffle areas (special aquatic site)

(7) Endangered species

(8) Cultural resources

(b) *Environmental requirements*

Environmental review and other consultation requirements applicable to the proposed action include:

(1) National Environmental Policy Act, as amended

(2) Clean Water Act, as amended

(3) Clean Air Act, as amended

(4) National Historical Preservation Act, as amended

(5) Fish and Wildlife Coordination Act

(6) Endangered Species Act, as amended

(7) California Surface Mining and Reclamation Act

(8) California Environmental Quality Act

#### 4. Availability of the EIS

The time of completion of the draft EIS is estimated to be June 1992.

Stanley G. Phernambucq,

LTC(P), EN, Commanding.

[FR Doc. 91-26812 Filed 11-6-91; 8:45 am]

BILLING CODE 3710-FS-M

#### Department of the Navy

##### Government-owned Inventions; Intent to Grant Exclusive Patent License

**AGENCY:** Department of the Navy, DOD.

**ACTION:** Intent to grant exclusive patent license; Richard A. Duffin.

**SUMMARY:** The Department of the Navy hereby gives notice of its intent to grant to Richard A. Duffin a revocable, nonassignable, exclusive license to practice the Government-owned invention described in U.S. Patent No. 4,789,547 "Fuel Efficient Propulsor for Outboard Motors" issued January 17, 1989.

Anyone wishing to object to the grant of this license has 60 days from the date of this notice to file written objections along with supporting evidence, if any. Written objections are to be filed with the Office of the Chief of Naval Research (Code OCCCIP), 800 North Quincy Street, Arlington, Virginia 22217-5000.

**FOR FURTHER INFORMATION CONTACT:** Mr. R. J. Erickson, Staff Patent Attorney, Office of the Chief of Naval Research (Code OCCCIP), 800 North Quincy Street, Arlington, Virginia 22217-5000, telephone (703) 696-4001.

Dated: October 30, 1991.

Wayne T. Baucino,

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

[FR Doc. 91-26884 Filed 11-6-91 8:45 am]

BILLING CODE 3810-AE-F

##### Government-owned Inventions; Intent to Grant Exclusive Patent License

**AGENCY:** Department of the Navy, DOD.

**ACTION:** Intent to grant exclusive patent license; U.S. Alcohol Testing of America, Inc.

**SUMMARY:** The Department of the Navy hereby gives notice of its nonassignable, exclusive license in the United States and certain foreign countries to practice the Government-owned invention described in U. S. Patent Application Serial No. 07/486,024, "Flow Immunosensor Method and Apparatus" filed February 23, 1990. Anyone wishing to object to the grant of this license has 60 days from the date of this notice to file written objections along with supporting evidence, if any. Written objections are to be filed with the Office of the Chief of Naval Research (Code OCCCIP), 800 North Quincy Street, Arlington, Virginia 22217-5000.

**FOR FURTHER INFORMATION CONTACT:** Mr. R. J. Erickson, Staff Patent Attorney, Office of the Chief of Naval Research (Code OCCCIP), 800 North Quincy Street, Arlington, Virginia 22217-5000, telephone (703) 696-4001.

Dated: October 30, 1991.

Wayne T. Baucino,

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

[FR Doc. 91-26885 Filed 11-6-91 8:45 am]

BILLING CODE 3810-AE-F

#### DEPARTMENT OF EDUCATION

##### Privacy Act of 1974

**AGENCY:** Department of Education.

**ACTION:** Notice of a new system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, as amended, the Department of Education publishes this notice of a new system of records known as the Jacob K. Javits Fellows System under the authority of title IX, part C of the Higher Education Act, as amended (20 U.S.C. 1134h-1134k). This notice includes proposed routine uses for the information contained in the system of records. The system will be used to select recipients for financial assistance, to pursue graduate study in the arts, humanities and social sciences. The Department seeks comments on the proposed routine uses for this system.

**DATES:** Comments on proposed routine uses for this system of records must be submitted by December 9, 1991. The Department filed a report of the new system of records with the Committee on Governmental Affairs of the Senate, the Committee on Government Operations of the House of Representatives, and the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) on November 4, 1991. This system of records will become effective after the 60-day period for OMB review of the system expires on January 3, 1992, unless OMB gives specific notice within the 60 days that the system is not approved for implementation or requests additional time for its review. The Department will publish any changes to the routine uses that are required as a result of the comments.

**ADDRESSES:** Comments on the proposed routine uses should be addressed to the Privacy Act Officer, Information Management and Compliance Division, Office of Information Resources Management, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5624, GSA Regional Office Building 3, Washington, DC 20202-4651. All comments submitted in response to this notice will be available for public inspection, during and after the comment period, in room 5624, GSA Regional Office Building 3, 7th and D Streets, SW., between the hours of 8:30 a.m. and 4 p.m., Monday through Friday of each week except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Diana Hayman, Program Manager, Jacob K. Javits Fellows Program, Office of Higher Education Programs, U.S. Department of Education, 400 Maryland Avenue, SW., Room 3022, GSA Regional Office Building 3, Washington, DC 20202-5251. Telephone: (202) 708-9415.

**SUPPLEMENTARY INFORMATION:** The Privacy Act of 1974 (see 5 U.S.C. 552a(e)(4)) requires the Department to publish in the Federal Register this notice of the a new system of records. The Department's regulations implementing the Privacy Act of 1974 are contained in the Code of Federal Regulations (CFR) at 34 CFR part 5b.

The Office of Higher Education Programs of the Office of Postsecondary Education is responsible for administering the Jacob K. Javits Fellows Program. The Program provides financial assistance to students of superior ability to pursue graduate studies in the arts, humanities, and social sciences.



Each year applicants are invited to compete for financial assistance. The applicants are evaluated by panels of distinguished scholars in the arts, humanities, and the social sciences selected by the Fellowship Board of the Jacob K. Javits Fellows Program. The evaluations of the applicants are stored in a filing cabinet and also processed in a personal computer system. The computer system is used to rank the applicants for further consideration by the Fellowship Board.

The Fellowship Board is appointed by the Secretary of Education and is composed of individuals representative of both public and private higher education. The principal function of the Fellowship Board is to establish general policies for the Program and oversee its operation. In addition, the Fellowship Board annually selects the percentage of fellowships to be awarded in each field, sets criteria for selection, appoints applicant selection panels, and prepares and submits reports on the program to Congress.

The system of records described in this notice consists of information about the applicants, including the scores awarded in the competition. The personal data on individuals is maintained only to that extent that such information is considered necessary to meet the purposes of the program. A year after the competition the unsuccessful applicants' records are destroyed. The applications and computerized data of the successful applicants are destroyed five years after final payment to the fellow, or after completion of audit-related activities or litigation, whichever is later.

Because of the nature of the requirements established and procedures used for storing, retrieving, and disclosing records, and the safeguards put into place against unauthorized access, it is highly unlikely that the privacy of any individual could be violated with respect to information maintained on such individual in this system of records.

Dated: November 4, 1991.

Michael J. Farrell,

Acting Assistant Secretary for Postsecondary Education.

The Acting Assistant Secretary for Postsecondary Education publishes notice of a new system of records to read as follows:

18-40-0037.

**SYSTEM NAME:**

Jacob K. Javits Fellows System.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

U.S. Department of Education, Office of Higher Education Programs, 7th and D Streets, SW., Washington, DC 20202-5153.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who apply for fellowships under the Jacob K. Javits Fellows Program.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, social security number, or nine digit identification number, date of birth, address, scholastic accomplishments, rating scores, reference letters, waivers to letters of reference.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Title IX, part C of the Higher Education Act of 1965, as amended (20 U.S.C. 1134h-1134K). The program regulations are found in 34 CFR part 650.

**PURPOSE(S):**

This system of records is maintained for the general purpose of administering the Jacob K. Javits Fellows Program, including selection of fellows, tracking their progress, and ensuring compliance with program requirements.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

The Department of Education (ED) may disclose information contained in a record in this system of records without the consent of the individual consistent with the following routine uses but only for a purpose which is compatible with the purpose for which the record was collected:

(a) *Evaluating the applicants.* Records are disclosed to the Fellowship Board and selection panel members in order to select fellows.

(b) *Congressional member disclosure.* ED may disclose personally identifiable information from this system of records to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

(c) *Litigation disclosure.* (1) Disclosure to the Department of Justice. If ED determines that disclosure of certain records to the Department of Justice is relevant and necessary to litigation and is compatible with the purpose for which the records were collected, ED may disclose those records as a routine use to the Department of Justice. Such a disclosure may be made in the event that one of the parties listed below is involved in the litigation, or has an interest in such litigation:

(i) ED, or any component of the Department; or

(ii) Any employee of ED in his or her official capacity; or

(iii) Any employee of ED in his or her individual capacity where the Justice Department has agreed to represent the employee; or

(iv) The United States where ED determines that the litigation is likely to affect the Department or any of its components.

(2) *Disclosure to a Court, Adjudicative Body or Potential Witnesses.* If ED determines that the disclosure of certain records to a court or adjudicative body before which ED is authorized to appear, an individual or entity designated by ED or otherwise empowered to resolve disputes, counsel or representative or to potential witnesses is relevant and necessary to litigation and is compatible with the purpose for which the records were collected, ED may disclose those records as a routine use to the court, adjudicative body, individual or entity, counsel or representative, or potential witnesses. Such disclosure may be made in the event that one of the parties listed below is involved in the litigation, or has an interest in the litigation:

(i) ED or any component of the Department; or

(ii) Any employee of ED in his or her official capacity; or

(iii) Any employee of ED in his or her individual capacity where ED has agreed to represent the employee; or

(iv) The United States where ED determines that the litigation is likely to affect the Department or any of its components.

(d) *FOIA advice disclosure.* In the event ED deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

(e) *Research disclosure.* When the appropriate official of ED determines that an individual or an organization is qualified to carry out specific research, that official may disclose information from this system of records to that researcher solely for the purpose of carrying out that research. The researcher shall be required to maintain Privacy Act safeguards with respect to such research.

(f) *Contract disclosure.* When ED contracts with a private firm for the purpose of computer data entry, collating, analyzing, aggregating or otherwise refining records in this system, relevant records will be



disclosed to the contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

#### DISCLOSURE TO CONSUMER REPORTING AGENCIES:

*Disclosure pursuant to 5 U.S.C. 552(a)(b)(12):* ED may disclose to a consumer reporting agency information regarding any Federal claim which is determined to be valid and overdue as follows: (1) The name, address, taxpayer identification number and other information necessary to establish the identity of the individual responsible for the claim; (2) the amount, status, and history of the claim; and (3) the program under which the claim arose. ED may disclose the information specified in this paragraph under 5 U.S.C. 552(a)(b)(12) after completing the procedures contained in subsection 31 U.S.C. 3711(f). A consumer reporting agency to which these disclosures may be made is defined at 31 U.S.C. 3701(a)(3).

#### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM.

##### STORAGE:

Records are maintained on access-controlled personal computers, and on file folders and on removable personal computer diskettes which are stored in file cabinets.

##### RETRIEVABILITY:

Records are indexed and retrieved by name of individual and social security number, or, for individuals who do not provide a social security number, other nine digit identification number.

##### SAFEGUARDS:

The computer data on personal computers is protected with access-control software. The personal computers are kept in office space that is locked during non-working hours. The file folders and removable personal computer diskettes are kept locked in file cabinets located in office space that is locked after hours. Users of the system are briefed on the need to safeguard the data and operating programs.

##### RETENTION AND DISPOSAL:

Records on successful applicants are destroyed five years after final payment, or after completion audit-related activities or litigation, whichever is later.

##### SYSTEM MANAGER AND ADDRESS:

Program Manager, Jacob K. Javits Fellows Program, Office of Higher Education Programs, U.S. Department of Education, 400 Maryland Avenue, SW.,

room 3022, GSA Regional Office Building 3, Washington, DC 20202-5251.

#### NOTIFICATION PROCEDURE:

If an individual wishes to determine whether a record exists for him or her in this system of records, the individual should provide the system manager his or her name date of birth, social security number or nine digit identification number. Requests for notification about whether this system contains information about an individual must meet the requirements of the Education Department's Privacy Act regulations, 34 CFR 5b.5.

#### RECORD ACCESS PROCEDURE:

If an individual wishes to gain access to record in this system of records, he or she should contact the system manager and provide information as described in the notification procedure. Requests for access to a record should reasonably specify the particular record content being sought. Requests for access to a record in this system of records must meet the requirements of the Education Department's Privacy Act regulations, 34 CFR 5b.5.

#### CONTESTING RECORD PROCEDURE:

Individuals desiring to contest information contained in a record in this system of records should contact the system manager. Requests for amendment of records may be made either in writing or in person, and should specify: (1) The system of records from which the record is to be retrieved; (2) the particular record he requestor is seeking to amend; (3) whether a deletion, an addition, or a substitution is being sought; and (4) the reason(s) for the requested change(s). Requestors should include in their requests any appropriate documentation supporting the requested change(s). For a complete statement of the procedures required for contesting a record, see the Education Department's Privacy Act regulations, 34 CFR 5b.7.

#### RECORD SOURCE CATEGORIES:

Information contained in the system will be obtained principally from individual applicants, references, and schools attended by the applicant.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 91-26941 Filed 11-6-91; 8:45 am]

BILLING CODE 4000-01-M

## DEPARTMENT OF ENERGY

### Bonneville Power Administration

#### Canby Area Service Project, Modoc County, CA Floodplain and Wetland Involvement

**AGENCY:** Bonneville Power Administration (BPA), Department of Energy (DOE).

**ACTION:** Notice of Floodplain and Wetland Involvement, Modoc County, California.

**SUMMARY:** BPA proposes to construct a 6- to 10-mile, 230-kV transmission line between its Malin-Warner 230-kV transmission line and the Surprise Valley Electrification Corporation's Canby Substation in Modoc County, California. BPA will construct a new substation adjacent to the existing substation. Three alternative routes identified for the transmission line cross vernal and riparian wetlands, and floodplains of two intermittent streams.

**FOR FURTHER INFORMATION CONTACT:** John Taves—EFBG, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon 97208.

**SUPPLEMENTARY INFORMATION:** Three alternative routes are under consideration for the location of the transmission line. The routes leave the Canby Substation vicinity on the west side of the town of Canby and move in a north, northwesterly, or northeasterly direction until they intersect the Malin-Warner transmission line. All of the routes cross the 100-year floodplain of an unnamed tributary to the Pit River flowing out of Howard's Gulch, and two of the routes cross the 100-year floodplain of Blacks Canyon Creek. Vernal and riparian wetlands located in sections 4, 10, 11, 12, 13, 15, 23, 24, and 25 of Township 42 North, Range 9 East; section 25 of Township 43 North, Range 9 East; and sections 17, 29, and 30 of Township 42 North, Range 10 East are crossed by the alternative routes. The floodplain(s) and wetlands will be spanned by the transmission line wherever possible, and at most eight wood pole H-frame structures would be placed in a floodplain, and none in a wetland. In accordance with DOE regulations for compliance with floodplain/wetland environmental review requirements (10 CFR part 1022), BPA will prepare a floodplain/wetland assessment to be incorporated in the environmental assessment of this proposed action. Maps and further information are available from BPA at the address shown above.



Issued in Portland, Oregon, on October 25, 1991.

Jack Robertson,

Acting Administrator, Bonneville Power Administration.

[FR Doc. 91-26931 Filed 11-6-91; 8:45 am]

BILLING CODE 6450-01-M

## Federal Energy Regulatory Commission

[Docket No. QF86-968-003]

### E.F. Oxnard, Inc., Application for Commission Recertification of Qualifying Status of a Cogeneration Facility

October 31, 1991.

On October 23, 1991, E.F. Oxnard, Inc. (Applicant) of 1230 Columbia Street, Suite 500, San Diego, California 92101, submitted for filing an application for recertification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's Regulations. No determination has been made that the submittal constitutes a complete filing.

The topping-cycle cogeneration facility is located in Oxnard, California, and includes a combustion turbine generator and a supplementary fired heat recovery boiler. Thermal energy recovered from the facility will be sold to Boskovich Farms, Inc. for use in its absorption refrigeration systems to provide cooling service for food storage, precooling of vegetables, and manufacture of ice for vegetable shipment.

The original certification was issued on October 22, 1987 [41 FERC ¶ 62,073 (1987)] and recertification was issued on April 5, 1989 [47 FERC ¶ 62,011 (1989)]. The instant recertification is requested due to Applicant's sale-leaseback arrangement of the facility with AT&T Credit Corporation.

Any person desiring to be heard or objecting to the granting of qualifying status should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed within 30 days after the date of publication of this notice in the *Federal Register* and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file

with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-26827 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP92-132-000, et al.]

### Tennessee Gas Pipeline Co., et al.; Natural Gas Certificate Filings

October 31, 1991.

Take notice that the following filings have been made with the Commission:

#### 1. Tennessee Gas Pipeline Co.

[Docket No. CP92-132-000]

Take notice that on October 28, 1991, Tennessee Gas Pipeline Company (Tennessee), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP92-132-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to provide a firm transportation service for Pittsburgh Corning Corporation (Pittsburgh Corning), an end user, under the blanket certificate issued in Docket No. CP87-115-000 pursuant to section 7 of the Natural Gas Act. Tennessee also requests a waiver of the first-come, first-served provisions of its open-access tariff in order to accord Pittsburgh Corning the same queue priority for purposes of scheduling and curtailment, all as more fully set forth in the request on file with the Commission and open to public inspection.

Tennessee states that pursuant to a transportation agreement dated July 31, 1989, as amended, it would transport up to 1,000 Dth per day for Pittsburgh Corning. Tennessee indicates that it would transport 1,000 Dth on an average day and 365,000 Dth annually. Tennessee further indicates that the natural gas would be transported from a receipt point located in the state of Mississippi and would be delivered in the state of Pennsylvania.

*Comment date:* December 16, 1991, in accordance with Standard Paragraph G at the end of this notice.

#### 2. Equitrans, Inc.

[Docket No. CP92-133-000]

Take notice that on October 29, 1991, Equitrans, Inc. (Equitrans), 3500 Park Lane, Pittsburgh, Pennsylvania 15275, filed in Docket No. CP92-133-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to provide an interruptible transportation service for Eastern American Energy Corporation under the

blanket certificate issued in Docket No. CP86-553-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Equitrans states that, pursuant to an agreement dated September 9, 1988, as amended, under its Rate Schedule ITS, it proposes to transport up to 1,316 MMBtu per day equivalent of natural gas. Equitrans states that it would transport 1,316 MMBtu on an average day and 100,000 MMBtu annually. Equitrans further states that the gas would be transported from West Virginia, and would be redelivered in Pennsylvania and West Virginia.

Equitrans advises that service under § 284.223(a) commenced September 1, 1991, as reported in Docket No. ST92-226-000.

*Comment date:* December 16, 1991, in accordance with Standard Paragraph G at the end of this notice.

#### 3. Midwestern Gas Transmission Co.

[Docket No. CP92-128-000]

Take notice that on October 28, 1991, Midwestern Gas Transmission Company (Midwestern), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP92-128-000 a request pursuant to §§ 157.205 and 157.212 of the Regulations under the Natural Gas Act for authorization to add three delivery points for a firm sales service presently provided by Midwestern to Northern Indiana Public Service Company (NIPSCO) under the certificate issued in Docket No. CP82-414-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request with the Commission and open to public inspection.

Midwestern states that it is presently serving NIPSCO at one delivery point under Midwestern's CD-1 rate schedule and the terms of a gas service contract between Midwestern and NIPSCO dated August 31, 1981. Midwestern indicates that the service contract provides for the sale and delivery by Midwestern and purchase and receipt by NIPSCO of 255,000 Mcf of natural gas per day. The application states that NIPSCO has requested and Midwestern has agreed to establish three existing interconnections in Vermillion and Will Counties, Illinois and Spencer County, Indiana as additional delivery points under the August 31, 1981 gas service contract.

Midwestern states that because the metering facilities at two of the delivery points proposed to be added are owned and operated by the interconnecting pipeline, and because of differentials in the day-to-day operating pressures of



these pipelines and the operating pressure of Midwestern's pipeline system. Midwestern cannot make a firm commitment to deliver gas for the account of NIPSCO under the CD-1 rate schedule on any particular day. Midwestern further states that its obligation to deliver gas at each of the three proposed delivery points must, therefore, be restricted to a best efforts basis.

*Comment date:* December 16, 1991, in accordance with Standard Paragraph G at the end of this notice.

#### 4. Mississippi River Transmission Corp. and Natural Gas Pipeline Co. of America

[Docket No. CP92-119-000]

Take notice that on October 23, 1991, Mississippi River Transmission Corporation (MRT), 9900 Clayton Road, St. Louis, Missouri 63124, and Natural Gas Pipeline Company of America (Natural), 701 East 22nd Street, Lombard, Illinois 60148, filed in Docket No. CP92-119-000 a joint application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon, partially, an exchange service, and a sales and transportation service, all effective April 1, 1991, all as more fully set forth in the application on file with the Commission and open to public inspection.

MRT states that in Docket No. CP75-226 it was authorized to deliver up to 200,000 Mcf per day of natural gas to Natural from MRT's interest in the Mills Ranch Field in Wheeler County, Texas pursuant to Rate Schedule X-13. Natural states that in Docket No. CP75-224 it was authorized to receive up to 200,000 Mcf per day of natural gas from MRT in Wheeler County, Texas and to redeliver to MRT at existing points of interconnection with MRT located in Clinton County, Illinois, Randolph County, Arkansas and Harrison County, Texas, 89 percent of the volumes delivered by MRT to Natural during the six months commencing April 1 each year and 43 percent of the volumes delivered by MRT to Natural during the six months commencing October 1 each year, provided that on an annual basis Natural redelivers to MRT 66 percent of the total volumes delivered to Natural from MRT, pursuant to Natural's Rate Schedule X-57. MRT and Natural state that they have agreed to reduce the maximum daily quantity from 200,000 Mcf to 15,000 Mcf and request permission and approval for such abandonment to be effective April 1, 1991.

In addition, MRT states that in Docket No. CP77-106 it was authorized to sell and deliver natural gas produced in the

Little Washita area in Grady County, Oklahoma, to Natural at an interconnection between MRT and Natural also located in Grady County, Oklahoma, pursuant to MRT's Rate Schedule X-16. Natural also states that in Docket No. CP77-131 it was authorized to transport up to 15,000 Mcf per day of natural gas from Grady County, Oklahoma, and to redeliver 75 percent of such volumes to MRT at an existing interconnection with MRT in Clinton County, Illinois or at MRT's option at an existing interconnection with MRT in Randolph County, Arkansas. It is stated that the remaining 25 percent of such volumes are sold to Natural. MRT and Natural state that they have agreed to abandon the sale of natural gas under Rate Schedule X-78 and the transportation of natural gas under Rate Schedules X-16, respectively, and request permission and approval for such abandonment to be effective on April 1, 1991.

*Comment date:* November 21, 1991, in accordance with Standard Paragraph F at the end of this notice.

#### Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirement of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion

believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 91-26828 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP89-251-018]

#### Alabama-Tennessee Natural Gas Co.; Notice of Proposed Changes in FERC Gas Tariff

November 1, 1991.

Take notice that Alabama-Tennessee Natural Gas Company ("Alabama-Tennessee") on October 30, 1991 tendered for filing various revisions to its FERC Gas Tariff, First Revised Volume No. 1 in order to conform its tariff with the Commission's October 24, 1991 Letter Order issued in this proceeding.

Alabama-Tennessee states that these tariff sheets are being tendered in order to modify the unauthorized delivery penalty provision set forth in section 3.7(c) of the General Terms and Conditions of Alabama-Tennessee's FERC Gas Tariff and to modify its substitution charge to avoid the possibility of a double recovery of fixed costs.

Alabama-Tennessee states that copies of the filing were served upon all its affected customers and interested public bodies, and upon all persons on the Commission's official service list established in the captioned docket.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission,



825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26829 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP88-211-020]

### **CNG Transmission Corp.; Compliance Filing**

November 1, 1991.

Take notice that CNG Transmission Corporation ("CNG"), on October 29, 1991, filed a letter with the Commission in this proceeding which asked the Commission to find that the Stipulation and Agreement filed in Docket No. RP90-143 on October 29, 1991, constitutes full compliance with the October 16, 1991, OPR letter order in this proceeding.

CNG states that copies of the filing were served upon parties to the proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26830 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. TA91-1-22-004, TM92-1-22-003, RP91-222-003 (not consolidated)]

### **CNG Transmission Corp.; Proposed Changes in FERC Gas Tariff**

November 1, 1991.

Take notice that CNG Transmission Corporation ("CNG"), on October 29, 1991, pursuant to section 4 of the

Natural Gas Act and Part 154 of the Commission's regulations, filed tariff sheets to supplement its tariff filing of October 23, 1991, in the referenced dockets by filing six (6) copies of the revised tariff sheets described in appendix A to the filing.

Additionally, CNG seeks to withdraw the tariff sheets filed on October 23, 1991.

CNG states that the purpose of this filing is to correct an inadvertent transpositional error that appeared on the tariff sheets filed on October 23, 1991.

CNG states that it has provided copies of its filing to its customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26831 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ92-1-21-001]

### **Columbia Gas Transmission Corp.; Proposed Changes in FERC Gas Tariff**

October 31, 1991.

Take notice that Columbia Gas Transmission Corporation (Columbia) on October 25, 1991, tendered for filing the following proposed changes to its FERC Gas Tariff, First Revised Volume No. 1, to be effective November 1, 1991.

Substitute Fourth Revised Eleventh Revised Sheet No. 26

Substitute Third Revised Sheet No. 26.1

Substitute Fourth Revised Eleventh Revised Sheet No. 26A

Substitute Third Revised Sheet No. 26A.1

Substitute Fourth Revised Eleventh Revised Sheet No. 26B

Substitute Second Revised Sheet No. 26B.1

Substitute Fourth Revised Tenth Revised Sheet No. 26C

Substitute Fourth Revised First Revised Sheet No. 26D

Substitute Twelfth Revised Sheet No. 163

Columbia states that the sales rates set forth on Substitute Third Revised Sheet No. 26.1 reflect an overall decrease of 33.72¢ per Dth in the

commodity rate, and a \$.006 increase in the demand rate (10.07¢ per Dth commodity increase over the October 1, 1991 filed rate and no change in the Demand). In addition, the transportation rates set forth on Substitute Fourth Revised Tenth Revised Sheet No. 26C reflect a decrease in the Fuel Charge component of .83 cents per Dth.

Columbia states that the purpose of the subject tariff sheets is to amend the Purchased Gas Cost Adjustment filed on October 1, 1991 and maintain the same effective date of November 1, 1991.

Columbia states that copies of the filing were served upon Columbia jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before November 7, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26832 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP89-250-007]

### **Columbia Gas Transmission Corp.; Report of Refunds**

October 31, 1991.

Take notice that on September 24, 1991, Columbia Gas Transmission Corporation (Columbia Gas) tendered for filing its refund report. Columbia Gas states that on May 24, 1991 it made lump sum refunds to its jurisdictional sales and transportation customers for the period April 1, 1990 through October 31, 1990 in the amount of \$30,915,828.00 (\$28,660,593.80 principal and \$2,255,234.20 interest) in the above referenced docket.

Columbia Gas states that the refunds were made in accordance with the terms of the September 21, 1990 Offer of Settlement filed in the above referenced docket and approved by the Commission on February 7, 1991.

Columbia Gas states that copies of the refund report and details of each customer's refund calculations were served upon all Columbia Gas's



customers and upon all interested state regulatory agencies.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 7, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-26833 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP89-249-005]

#### **Columbia Gulf Transmission Co.; Report of Refunds**

October 31, 1991.

Take notice that on September 27, 1991, Columbia Gulf Transmission Company (Columbia Gulf) tendered for filing its refund report. Columbia Gulf states that on May 24, 1991 it made lump sum refunds to its jurisdictional transportation customers for the period April 1, 1990 through October 31, 1990 in the amount of \$7,388,259.76 (\$6,854,616.98 principal and \$533,642.78 interest) in the above referenced docket.

Columbia Gulf states that the refunds were made in accordance with the terms of the September 21, 1990 Offer of Settlement filed in the above referenced docket and approved by the Commission on February 7, 1991.

Columbia states that copies of the refund report and details of each customer's refund calculations were served upon all Columbia's customers and upon all interested state regulatory agencies.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 7, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the

Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-26834 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP88-44-021]

#### **El Paso Natural Gas Co.; Payment of Refunds**

November 1, 1991.

Take notice that El Paso Natural Gas Company ("El Paso"), on October 30, 1991, tendered for filing in compliance with the provisions of the Stipulation and Agreement in Settlement of Rate and Related Proceedings ("Stipulation and Agreement") approved by the Federal Energy Regulatory Commission ("Commission") by orders issued March 20, 1991, and August 14, 1991, its Report of Refunds for transportation and sales services for the period July, 1988, through August, 1991. El Paso states that because of the structure of the Stipulation and Agreement, refund checks or wire transfers were appropriate and thus distributed only to its interstate pipeline system transportation customers entitled thereto.

El Paso states that the Report of Refunds reflects the transportation and sales refunds, calculated and distributed in accordance with sections 4.2, 4.3 and 4.4 of article IV and section 6.8(b) of article VI of the Stipulation and Agreement inclusive of interest calculated in accordance with § 154.67(c)(2)(iii) of the Commission's Regulations, through October 14, 1991. The transportation and sales refund calculations were based on the refund rates as specified in El Paso's Stipulation and Agreement designated as Period 1 Rates for the period July, 1988 through August, 1990 and Period 2A Rates, for the period September, 1990 through August, 1991.

El Paso states that it distributed on October 15, 1991, to its transportation customers entitled thereto refunds aggregating \$277,972,330.24 inclusive of interest calculated through October 14, 1991; however, El Paso states that the actual transportation refund amount totals \$288,548,225.99 and that a credit in the amount of \$10,573,895.75 was applied to the actual transportation refund amount.

El Paso states that the sales refund amount totalled \$78,157,653.96, inclusive of interest calculated in accordance with said § 154.67(c)(2)(iii) through October 14, 1991. El Paso states that pursuant to paragraph 6.8 of article VI of the

Stipulation and Agreement, the sales refund amount of \$78,157,653.96 was applied to the balance of Account 191. El Paso also states that pursuant to section 10.2 of article X of the Stipulation and Agreement, it applied the otherwise applicable lawful rate to volumes originally priced at the NGPA section 104 replacement contract rate to its company-owned production from and after October 1, 1983. El Paso states that such recalculation resulted in a \$128,647.94 refund due El Paso's customers and such amount was also applied to reduce the balance of Account 191.

El Paso states that pursuant to section 6.8(b) of article VI of the Stipulation and Agreement the remaining balance of Account 191, in the amount of \$10,648,618.02 was allocated among individual sales customers to be direct billed as provided in section 6.9. The Account 191 amounts allocated to certain sales customers were further reduced to those sales customers who are also transportation customers of El Paso by crediting the allocated amounts against the transportation refund amounts due that customer.

El Paso states that pursuant to section 7.3 of article VII of the Stipulation and Agreement, it calculated the "true-up" for take-or-pay buyout and buydown costs. The true-up calculation was computed on actual throughput surcharge collections (where less than the maximum settled tariff rate was charged, the discount from such rate was applied to the throughput surcharge component of such total rate) as compared to the straightline amortization for the period December, 1988 through August, 1991. Such calculation resulted in an undercollection in the amount of \$3,494,138.19.

El Paso states that copies of the report were served on all parties of record in Docket No. RP88-44-000, *et al.* and otherwise upon all interstate pipeline system transportation and sales customers of El Paso who received a refund distribution and all interested state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding.



Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26835 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-16-000]

**El Paso Natural Gas Co. Tariff Filing**

October 31, 1991.

Take notice that on October 28, 1991, El Paso Natural Gas Company ("El Paso"), filed, pursuant to part 154 of the Federal Energy Regulatory Commission ("Commission") Regulations Under the Natural Gas Act and section 22.6 contained in the General Terms and Conditions of its Second Revised Volume No. 1 Tariff, Third Revised Sheet No. 100B reflecting the confidential nature of the Gas Inventory Charge and Gas Cost Ceiling Charge rates to be effective November 1, 1991.

El Paso states that on August 30, 1991, at Docket No. RP88-44-019, El Paso tendered certain tariff sheets, to be effective September 1, 1991, in compliance with the "Stipulation and Agreement in Settlement of Rate and Related Proceedings" filed August 31, 1990, as amended October 5, 1990, at Docket No. RP88-44-000, *et al.* El Paso states that included in the tariff sheets comprising the filing were certain tariff sheets establishing a new section 22 contained in the General Terms and Conditions of El Paso's Volume No. 1 Tariff which sets forth provisions for a Gas Inventory Charge mechanism. Section 22.6, Filing with Commission, states that "Seller shall file with the Commission at least seventy-two (72) hours before the effective date, . . . the Gas Inventory Charge rates and the Gas Cost Ceiling Charge rates and the period(s) during which such rates will be in effect." El Paso states that it intends to implement a GIC Sales Service Agreement with Southwest Gas Corporation to be effective November 1, 1991. Accordingly, El Paso states that it is tendering for filing and acceptance Third Revised Sheet No. 100B to be effective November 1, 1991 and is requesting confidential treatment of the Gas Inventory Charge and Gas Cost Ceiling Charge rates until December 1, 1991.

El Paso respectfully requests that, for the same reasons set forth in the Commission's order on rehearing in Natural Gas Pipeline Company of America, Docket Nos. CP89-1281-010 and TA90-1-26-003, issued June 11, 1991, the Commission keep such rates to

be effective November 1, 1991 confidential until December 1, 1991. El Paso proposes to file with the Commission each month thereafter the Gas Inventory Charge rates and Gas Cost Ceiling Charge rates in effect for that particular month and will request that the Commission keep the rates confidential until the end of the month. El Paso states that at the end of the month it will post on its electronic bulletin board the Gas Inventory Charge and the Gas Cost Ceiling Charge rates which were in effect for that particular month.

El Paso states that it is submitting concurrently therewith, but under separate cover letter, a schedule setting forth its actual Gas Inventory Charge and Gas Cost Ceiling Charge rates for the month of November, 1991 requesting that, pursuant to §§ 385.1112 and 388.112 of the Rules of Practice and Procedure, such information be treated as confidential and privileged.

El Paso respectfully requests that the Commission accept the tendered tariff sheet for filing and permit it to become effective on November 1, 1991.

El Paso states that copies of the filing were served upon all interstate pipeline system sales customers of El Paso and interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before November 7, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 91-26836 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. TQ92-2-24-000 and TQ92-2-24-001]

**Equitrans, Inc.; Proposed Changes In FERC Gas Tariff**

November 1, 1991.

Take notice that Equitrans, Inc. (Equitrans) on October 30, 1991, tendered for filing the following tariff

sheets to its FERC Gas Tariff, Original Volume No. 1, to become effective December 1, 1991:

Thirty-First Revised Sheet No. 10  
Twenty-Second Revised Sheet No. 34

As alternate tariff sheets, Equitrans submits the following:

Alternate Thirty-First Revised Sheet No. 10  
Alternate Twenty-Second Revised Sheet No. 34

Equitrans states that the primary tariff sheets are being filed in accordance with §§ 154.308 and 154-304(c) of the Commission's Regulations and section 19 of Equitrans' FERC Gas Tariff, Original Volume No. 1.

Equitrans states that the alternate tariff sheets are being filed to implement the pending certification before the Commission in Docket No. CP92-109-000, to provide firm sales service of up to 50,000 dekatherm (Dth) per day of natural gas to Texas Eastern Transmission Corporation during the winter season of November through March.

Equitrans states that a copy of its filing has been served upon its purchasers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 91-26837 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-110-004]

**Great Lakes Gas Transmission Limited Partnership; Proposed Changes In FERC Gas Tariff**

November 1, 1991.

Take notice that Great Lakes Gas Transmission Limited Partnership ("Great Lakes") on October 30, 1991 tendered for filing revised sheets to its



FERC Gas Tariff to be effective April 1, 1991.

Great Lakes states that these tariff sheets were filed to amend a previously filed, and accepted, tariff filing to reflect the appropriate rates and tariff sheet pagination since the filing of Great Lakes' RP90-20 settlement rates on October 23, 1991, to be effective May 1, 1990.

Great Lakes states that copies of the filing were served on all of Great Lakes' customers and the Public Service Commissions of Minnesota, Michigan and Wisconsin.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26838 Filed 11-6-91; 8:45 am]  
BILLING CODE 6717-01-M

[Docket No. RP91-144-001]

**Great Lakes Gas Transmission Limited Partnership; Proposed Changes in FERC Gas Tariff**

November 1, 1991.

Take notice that Great Lakes Gas Transmission Limited Partnership ("Great Lakes") on October 30, 1991 tendered for filing revised sheets to its FERC Gas Tariff to be effective June 1, 1991.

Great Lakes states that these tariff sheets were filed to amend a previously filed, and accepted, tariff filing to reflect the appropriate rates and tariff sheet pagination since the filing of Great Lakes' RP90-20 settlement rates on October 23, 1991, to be effective May 1, 1990.

Great Lakes states that copies of the filing were served on all of Great Lakes' customers and the Public Service Commissions of Minnesota, Michigan and Wisconsin.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules

of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26839 Filed 11-6-91; 8:45 am]  
BILLING CODE 6717-01-M

[Docket No. RP91-148-001]

**Great Lakes Gas Transmission Limited Partnership; Proposed Changes in Gas Tariff**

November 1, 1991.

Take notice that Great Lakes Gas Transmission Limited Partnership ("Great Lakes") on October 30, 1991 tendered for filing revised sheets to its FERC Gas Tariff to be effective June 1, 1991.

Great Lakes states that these tariff sheets were filed to amend a previously filed, and accepted, tariff filing to reflect the approximate rates and tariff sheet pagination since the filing of Great Lakes' RP90-20 settlement rates on October 23, 1991, to be effective May 1, 1990.

Great Lakes states that copies of the filing were served on all of Great Lakes' customers and the Public Service Commissions of Minnesota, Michigan and Wisconsin.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26840 Filed 11-6-91; 8:45 am]  
BILLING CODE 6717-01-M

[Docket No. TA92-1-53-001]

**K N Energy, Inc.; Proposed Changes in FERC Gas Tariff**

November 1, 1991.

Take notice that K N Energy, Inc. ("K N") on October 29, 1991 requested permission to withdraw from its annual PGA the report entitled "Order 451 Negotiations" (Schedule D1, Text ID10) and requested a waiver with regard to segregating billing adjustments by debit and credit prior to calculation of carrying charges.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26841 Filed 11-6-91; 8:45 am]  
BILLING CODE 6717-01-M

[Docket No. TA91-2-15-002]

**Mid Louisiana Gas Co.; Compliance Filing**

October 31, 1991.

Take notice that Mid Louisiana Gas Company ("Mid Louisiana") on October 28, 1991, tendered for filing as part of First Revised Volume No. 1 of its FERC Gas Tariff the Tariff Sheets and proposed effective dates as set forth below:

	Superseding	Proposed effect. date
Sub. Eighty-Fourth Revised Sheet No. 3a.	Eighty-Third Revised Sheet No. 3a.	Sept. 1, 1991.
Sub. Eighty-Fifth Revised Sheet No. 3a.	Sub. Eighty-Fourth Revised Sheet No. 3a.	Sept. 1, 1991.
Sub. Eighty-Sixth Revised Sheet No. 3a.	Sub. Eighty-Fifth Revised Sheet No. 3a.	Oct. 1, 1991.
Sub. Eighty-Seventh Revised Sheet No. 3a.	Sub. Eighty-Sixth Revised Sheet No. 3a.	Nov. 1, 1991.



Mid Louisiana states that the purpose of the filing of the Tariff Sheets is to reflect a revision in its unrecovered purchased gas cost surcharge in compliance with the Commission's order issued on September 27, 1991.

Mid Louisiana states that copies of this filing have been mailed to Mid Louisiana's jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 7, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26842 Filed 11-6-91; 8:45 am]  
BILLING CODE 6717-01-M

[Docket No. TQ92-1-27-000]

**North Penn Gas Co.; Proposed Changes in FERC Gas Tariff**

November 1, 1991.

Take notice that North Penn Gas Company (North Penn) on October 30, 1991, tendered for filing Ninth Revised Sheet No. 3A to its FERC Gas Tariff, First Revised Volume No. 1.

North Penn states that the revised tariff sheet is being filed pursuant to section 14 of the General Terms and Conditions of North Penn's FERC Gas Tariff to reflect changes in the cost of gas for the period December 1, 1991 through February 29, 1992 and is proposed to be effective December 1, 1991. The proposed change reflects a decrease in the average cost of gas for the G-1 Rate Schedule of \$1.41086 per Mcf.

While North Penn believes that no other waivers are necessary in order to permit this filing to become effective December 1, 1991, as proposed, North Penn respectfully requests waiver of any of the Commission's Rules and Regulations as may be required to permit this filing to become effective December 1, 1991.

North Penn states that copies of this letter of transmittal and all enclosures are being mailed to each of North Penn's jurisdictional customers and sta-

commissions shown on the attached service list.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before November 12, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26843 Filed 11-6-91; 8:45 am]  
BILLING CODE 6717-01-M

[Docket No. TQ92-1-28-000]

**Panhandle Eastern Pipe Line Co.; Proposed Changes in FERC Gas Tariff**

November 1, 1991.

Take notice that Panhandle Eastern Pipe Line Company (Panhandle) on October 31, 1991, tendered for filing the following revised tariff sheets listed to its FERC Gas Tariff, Original Volume No. 1:

2nd / Eighty-Eighth / Sheet No. 3-A  
2nd / Second Revised Sheet No. 3-A.1  
2nd / Sixty-Fifth Revised No. 3-B  
2nd / Twelfth Revised Sheet No. 3-B.1

The proposed effective date of these tariff sheets is December 1, 1991.

Panhandle states that these tariff sheets filed herewith reflect a commodity rate increase of 27.84¢ in the projected purchased gas cost component computed in accordance with section 18.2 of the General Terms and Conditions of Panhandle's tariff. The revised tariff sheets filed herewith also reflect the following changes to Panhandle's D1 and D2 demand rates: (1) An increase of \$0.22 for D1 and (2) no change for D2 in accordance with section 18.4 of the General Terms and Conditions of Panhandle's tariff (pipeline suppliers' demand costs).

Panhandle further states the above referenced tariff sheets are being filed in accordance with § 154.308 (Quarterly PGA Filing) of the Commission's Regulations and pursuant to sections 18.1 and 18.4 (Purchased Gas Demand Rate Adjustments by Pipeline Suppliers) of Panhandle's FERC Gas Tariff, Original Volume No. 1 to reflect the

changes in Panhandle's jurisdictional sales rates effective December 1, 1991.

Panhandle states that copies of its filing have been served on all jurisdictional sales customers and applicable state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with such motions §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before November 12, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26844 Filed 11-6-91; 8:45 am]  
BILLING CODE 6717-01-M

[Docket Nos. RP91-53-006]

**Panhandle Eastern Pipe Line Co.; Proposed Changes in FERC Gas Tariff**

November 1, 1991.

Take notice that Panhandle Eastern Pipe Line Company (Panhandle) on October 29, 1991, tendered for filing the revised tariff sheets to its FERC Gas Tariff, Original Volume No. 1 and Original Volume No. 2, as reflected on appendix A attached to the filing.

The subject tariff sheets bear a proposed effective date on November 1, 1991.

On July 10, 1991 Panhandle submitted an Offer of Settlement in connection with the above-referenced proceedings. The Commission issued an order on August 2, 1991 which approved the Stipulation and Agreement dated July 10, 1991. An order granting Requests for Clarification and Denying Request for Rehearing was issued September 25, 1991.

Pursuant to article II, section 2 of the Settlement, Panhandle submitted a report (including supporting workpapers) which shows: (a) The determination of repayment amounts calculated in accordance with article II, section 3 and (b) the determination of amounts which shall be paid to Panhandle calculated in accordance with Article II, section 4. The revised



tariff sheets included in appendix A herein reflect the actual amounts due from customers governed by article II of the Settlement and the Volumetric Surcharge pursuant to article II, section 8.

On June 28, 1991 in Docket No. RP91-165 the Commission approved revised tariff sheets which permitted panhandle to implement a system of electronic funds transfer for payments by its sales and transportation customers. Accordingly, Panhandle has updated Tariff Sheet No. 43-14.4 to reflect payments by electronic funds transfer.

Panhandle states that the revised tariff sheets also reflect Panhandle's (1) Quarterly PGA filing effective September 1, 1991 in Docket No. TQ91-4-28-000 and TM91-10-28-000, and (2) Annual Charge Adjustment (ACA) filed in Docket No. TM91-1-28-000 and made effective October 1, 1991.

Panhandle states that copies of the filing has been sent to all affected sales and transportation customers, affected state commissions and all parties on the service list in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26845 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ92-1-30-000]

#### Trunkline Gas Co.; Proposed Changes in FERC Gas Tariff

November 1, 1991.

Take notice that Trunkline Gas Company (Trunkline) on October 31, 1991 tendered for filing the following revised tariff sheet to its FERC Gas Tariff, Original Volume No. 1:

Eighty-Eighth Revised Sheet No. 3-A

The proposed effective date of this revised tariff sheet is December 1, 1991.

Trunkline states that the instant filing reflects a commodity rate decrease of

(11.76¢) per Dt. In projected purchased gas cost component.

Trunkline states that the tariff sheet is being filed in accordance with § 154.308 (quarterly PGA filing) of the Commission's Regulations and pursuant to section 18 (Purchase Gas Adjustment Clause) of the General Terms and Conditions in Trunkline's FERC Gas Tariff, Original Volume No. 1. Trunkline states that copies of this filing have been served on all jurisdictional sales customers and applicable state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before November 12, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26846 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-54-007]

#### Trunkline Gas Co.; Proposed Changes in FERC Gas Tariff

November 1, 1991.

Take notice that Trunkline Gas Company (Trunkline) on October 29, 1991, tendered for filing the revised tariff sheets to its FERC Gas Tariff, Original Volume Nos. 1 and 2 as reflected in appendix A attached to the filing.

The subject tariff sheets bear a proposed effective date of November 1, 1991.

Trunkline states that on July 10, 1991 Trunkline submitted an Offer of Settlement in connection with the above-referenced proceeding. The Commission issued an order on August 2, 1991 which approved the July 10, 1991, Stipulation and Agreement (Settlement). Pursuant to article IV of Trunkline's Settlement, the effectiveness of Trunkline's Settlement was dependent on Commission approval of Panhandle

Eastern Pipe Line Company's Stipulation and Agreement dated July 10, 1991 in Docket No. RP91-52-000 and Docket No. RP91-53-000 (and related proceedings). That Stipulation and Agreement, and Trunkline's Settlement as well, became effective October 25, 1991.

Trunkline further states that pursuant to article II, section 2 of the Settlement, Trunkline is submitting a detailed report (including supporting workpapers) showing the determination of amounts which shall be paid to Trunkline calculated in accordance with article II, section 4, and the determination of repayment amounts calculated in accordance with article II, section 3. The revised tariff sheets included in appendix A also reflect the actual amounts due from customers as governed by article II, section 4 and the volumetric surcharge pursuant to article II, section 8 of the Settlement.

The revised tariff sheets also reflect Trunkline's Flex PGA filed in docket No. TF92-1-30-000 to be effective November 1, 1991.

Trunkline states that copies of the filing has been sent to all affected sales and transportation customers, affected state commissions and all parties on the service list in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26847 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ92-1-56-000]

#### Valero Interstate Transmission Co.; Proposed Changes in FERC Gas Tariff

November 1, 1991.

Take notice that Valero Interstate Transmission Company ("Vitco"), on October 31, 1991 tendered for filing the following tariff sheet as required by



Orders 483 and 483-A containing changes in Purchased Gas Cost Rates pursuant to such provisions:

*FERC Gas Tariff, First Revised Volume No. 2*  
1st Revised Sheet No. 6

Vitco states that this filing reflects changes in its purchased gas cost rates pursuant to the requirements of Orders 483 and 483-A. The change in rates to Rate Schedule S-3 includes an increase in purchased gas cost of \$0.6700 per MMBtu.

The proposed effective date of the above filing is December 1, 1991. Vitco requests a waiver of any Commission order or regulations which would prohibit implementation by December 1, 1991.

Any person desiring to be heard or protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before November 12, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26848 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-21-000]

#### **Williams Natural Gas Co.; Proposed Changes in FERC Gas Tariff**

November 4, 1991.

Take notice that Williams Natural Gas Company (WNG) on November 1, 1991, tendered for filing the following tariff sheets to be included in its FERC Gas Tariff, First Revised Volume No. 1:

Third Revised Sheet Nos. 116 and 117  
Second Revised Sheet Nos. 120 and 121  
First Revised Sheet Nos. 127 through 129, 205, 207, 212 through 221, 232, 233 and 246

WNG states that the purpose of this filing is to resolve certain tariff issues which had been raised by parties and had been set for hearing in Docket No. RP89-183, *et al.* The specific tariff changes are described in the Statement of the Nature, Reasons and Basis for Proposed Tariff Changes. WNG requests

an effective date of December 1, 1991 for all tendered tariff sheets.

WNG states that copies of its filing were served by overnight express mail to the active parties in Docket No. RP89-183, *et al.*, and by regular mail to all jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with § 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before November 8, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26906 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-177-003]

#### **Wyoming Interstate Co., Ltd.; Compliance Filing**

October 31, 1991.

Take notice that on October 10, 1991 Wyoming Interstate Company, Ltd. (WIC) pursuant to the Commission's order issued September 26, 1991, submits open season procedures and tariff provisions setting forth the form for transportation service requests for interruptible transportation service. WIC states that the procedures will apply to requests for interruptible service under both subpart B of part 284 of 18 CFR (section 311 transportation) and subpart G. WIC states that although WIC has not yet accepted the open access blanket certificate granted by the Commission in Docket No. RP90-706, this open season, which will commence immediately and continue through October 24, 1991, will be used to establish the priority of service dates that will apply to subpart G interruptible transportation service when it is initiated.

WIC also tendered for filing as part of its FERC Gas Tariff, Original Volume No. 2 the following tariff sheets with the effective date of July 1, 1991:

Original Sheet No. 25  
Original Sheet No. 26

Original Sheet No. 27

WIC states that it has provided a copy of the filing to each party on the Commission's official service lists in Docket Nos. RP91-177 and CP90-706, and to all shippers that are receiving or who have requested interruptible transportation on WIC.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 7, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 91-26849 Filed 11-6-91; 8:45 am]

BILLING CODE 6717-01-M

#### **Office of Hearings and Appeals**

##### **Issuance of Decisions and Orders; Week of August 26, Through August 30, 1991**

During the week of August 26 through August 30, 1991, the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

##### **Appeals**

*Peter Almqvist, 08/29/91, HFA-0303*

Peter Almqvist filed an Appeal from a denial by the Director of the Office of Intelligence Analysis and Support of a request for information that he filed under the Freedom of Information Act (FOIA). In his Appeal, Mr. Almqvist challenged the DOE's refusal to acknowledge the existence of documents responsive to his request, and requested copies of the unclassified portions of the documents. The DOE determined that it would now confirm that it does possess responsive documents. Nevertheless, it further determined that these documents continue to be properly classified in their entirety and are therefore exempt from mandatory disclosure pursuant to Exemption 1 of the FOIA. Accordingly,



the appeal was granted in part and denied in part.

*Robert D. Carrell, 08/27/91, LFA-0140*

Robert D. Carrell filed an Appeal from a determination issued by the Richland Operations Office concerning a request for information which he submitted under the Privacy Act (PA). Carrell sought his vendor access records from Westinghouse Hanford Company (WHC), the prime contractor at Richland. Richland withheld Carrell's vendor access investigation records on the basis that these records were not subject to the PA. The DOE determined that the records were not created pursuant to WHC's contract with the DOE and, therefore, were not subject to the PA. Accordingly, the appeal was denied.

#### Remedial Order

*Powerine Oil Company, 08/30/91, HRO-0085*

Powerine Oil Company (Powerine) filed a Statement of Objections to a Proposed Remedial Order (PRO) issued to it on July 22, 1982 by the Economic Regulatory Administration (ERA). The PRO alleged that Powerine, a refiner, violated 10 CFR 212.83 by charging prices in excess of maximum allowable levels during the period August 20, 1973 through September 30, 1979, in its sales of motor gasoline and No. 2 oils. The ERA had originally requested that Powerine be ordered to refund \$12,225,606, plus interest. However, the ERA subsequently amended the PRO, and alleged a smaller amount of overcharges. In considering the case, the DOE examined many complex arguments about the proper interpretation of the former refiner price regulations, and their application to Powerine's specific business operations. The DOE found that Powerine had failed to meet its burden of coming forward with evidence to contravene the prima facie regulatory violations specified in the PRO. Accordingly, a Final Remedial Order was issued which directed Powerine to remit overcharges totalling \$7,956,934, plus interest to the United States Treasury.

#### Refund Applications

*Day & Zimmermann, Inc., 08/29/91, RF272-77408*

The DOE issued a Decision and Order denying a refund from the crude oil overcharge funds to Day & Zimmermann, Inc. (Day), a private contractor for the Department of the Army (Army). Through a cost-plus contract with the Army during the refund period, Day was reimbursed for all petroleum purchases it made in the

operation of an Army ammunition plant. Despite Day's offer to credit any refund granted back to the Army, the DOE determined that Day was not the proper recipient of a refund.

*Gulf Oil Corporation/Dunkirk Aviation Sales & Service, 08/30/91 RR300-45*

The DOE issued a Decision and Order concerning the Motion for Reconsideration filed by Dunkirk Aviation Sales & Service (Dunkirk) in the Gulf proceeding. In its Motion, Dunkirk sought a refund based on gallons for which it did not receive a refund in its original Application. In claiming these additional gallons, Dunkirk cited a customer listing which demonstrated that Dunkirk purchased more refined petroleum product than it had estimated in its original Application. Dunkirk explained why the customer listing was more accurate than its estimate, and certified that the Gulf figure was reasonable. The DOE granted Dunkirk a refund of \$54.

*Sauvage Gas Company, Inc./Joel Wilkinson, Assignee of H.C. Oil Company, 08/26/91, RR308-8*

The DOE issued a Decision and Order granting in part and denying in part a Motion for Reconsideration submitted by Joel Wilkinson, Assignee of H.C. Oil Company (H.C. Oil) in the Sauvage Gas Company, Inc. (Sauvage) special refund proceeding. In two prior Decisions, the DOE found that H.C. Oil was a spot purchaser of Sauvage petroleum products and, therefore, was not entitled to a refund. In the present Motion for Reconsideration, H.C. Oil stated that its purchases should be evaluated only with respect to the portion of the refund period in which it was in business. The DOE agreed with H.C. Oil. On the basis of the DOE's evaluation of H.C. Oil's purchases during the shortened period, it determined that H.C. Oil was a spot purchaser of propane, but a regular purchaser of butane and natural gasoline. The propane portion of H.C. Oil's Motion was denied, and the butane and natural gasoline portions were granted. The total volume of Sauvage petroleum products approved in this Decision was 2,169,807 gallons, and the total refund granted was \$6,218 (\$4,040 in principal and \$2,178 in interest).

*Stan's Union Service Mid-Valley Petroleum Corp., 08/29/91 RF272-26539, RF272-28038*

The DOE issued a Decision and Order concerning two Applications for Refund filed in the Subpart V crude oil special refund proceeding. Each applicant was a reseller or retailer of petroleum products during the period August 19, 1973 through January 27, 1981. Because

neither Applicant demonstrated that it was injured due to the crude oil overcharges, the DOE determined that each was ineligible for a crude oil refund and denied the Applications.

*Texaco Inc./Maitland Texaco, 08/29/91 RF321-1666, RF321-9041*

The DOE issued a Decision and Order concerning two Applications for Refund filed in the Texaco Inc. special refund proceeding by the owners of a retail outlet that was a direct purchaser of Texaco refined products. One application, filed by Robert Devenport, was denied on the grounds that the applicant had failed to establish that he operated the station at any time during the refund period. The other application, filed by Clifford Chin, the owner of the outlet during part of the refund period, was approved. Mr. Chin did not seek a refund greater than the \$10,000 small claims threshold established in the Texaco proceeding; accordingly he was not required to demonstrate injury. The total refund amount granted in this Decision is \$3,095 representing \$2,453 in principal and \$624 in interest.

#### Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Alma School District <i>et al.</i>	RF272-78807	8/30/91
Atlantic Richfield Co./Joseph Schroeder <i>et al.</i>	RF304-3800	8/28/91
Atlantic Richfield Co./Wilbanks Oil Co., Inc. <i>et al.</i>	RF304-6236	8/30/91
County of Monroe	RF272-65307	8/26/91
Dickerson, Inc.	RF272-69560	8/30/91
E.D.G., Inc./Department of Water and Power.	RF311-13	8/29/91
E.D.G., Inc./Rocky Home Dairy, Inc.	RF311-1	8/30/91
Fred L. Morgan	RC272-135	8/27/91
George L. Wurnig	RC272-134	8/29/91
Gulf Oil Corp./Chasteny Oil Co.	RF300-17479	8/29/91
Gulf Oil Corp./Hide-A-Way-Lake <i>et al.</i>	RF300-16300	8/28/91
Gulf Oil Corp./Hughes Main Street Gulf <i>et al.</i>	RF300-11621	8/29/91
Gulf Oil Corp./Jenny Oil Co. <i>et al.</i>	RF300-11926	8/29/91
Gulf Oil Corp./Ryder Energy Distribution.	RF300-17436	8/29/91
Gulf Oil Corp./Turnage Grocery <i>et al.</i>	RF300-16605	8/28/91
Hastings Area School System <i>et al.</i>	RF272-81621	8/28/91
Kerkhoven-Murdock-Sunberg School District <i>et al.</i>	RF272-78713	8/29/91
L.H. Bossier, Inc.	RF272-72085	8/30/91
L.H. Bossier, Inc.	RD272-72085	



Lilly Industrial Coatings, Inc.	RF272-63021	8/27/91
Lilly Industrial Coatings, Inc.	RD272-63021	
MGM Transport Corp.	RF272-76729	8/27/91
Murphy Oil Corp./Lloyd R. Crais Oil Co., Inc.	RF309-1350	8/30/91
Pinckneyville Comm. School District et al.	RF272-81611	8/27/91
Shell Oil Co./Grand & Sidney Shell et al.	RF315-6242	8/28/91
Tesoro Petroleum Corp./H.G. Seeley Construction Corp. et al.	RF326-200	8/26/91
Texaco Inc./Bernardo's Texaco et al.	RF321-815	8/27/91
Texaco Inc./Lewis Construction Co. et al.	RF321-9700	8/29/91
Texaco Inc./Lindley Oil Co. et al.	RF321-6583	8/28/91
Texaco Inc./Steve's Star Texaco et al.	RF321-7109	8/27/91
Texaco Inc./Sunset Blvd. Texaco et al.	RF321-9402	8/26/91
Texaco Inc./Vestal's Texaco et al.	RF321-8423	8/28/91
Thief River Falls I.S.D. #564.	RC272-136	8/29/91

## DISMISSALS

The following submissions were dismissed:

Name	Case No.
A.G. Van Metre	RF272-59577
Alumax, Inc.	RF272-75316
Baca County	RF272-58111
Bond County C U School District #2	RF272-79303
Bratz Oil Corp.	RF321-6319
City of Vicksburg	RF321-9702
Clay Gasser Texaco	RF321-123
Cloverland ARCO	RF304-9888
D&R Market	RF309-1185
Davis Fuels, Inc.	RF321-9561
Department of VA Medical Center	RF272-88724
Department of Water	RF336-23
Foster County, ND	RF272-85963
Freeway Service Center, Inc.	RF304-10746
Infotech Management, Inc.	RF272-61042
Keller's Atlantic	RF304-12064
Lyons Texaco	RF321-9505
McCullum's Travel Plaza	RF321-3200
Metro Truck Plaza	RF321-3199
Pennington Transfer & Storage	RF272-59579
Pitts and Braden, Inc.	RF304-10577
Poplar White Truck, Inc.	RF304-12052
Prairie Village Skelly Service	RF321-3198
Prince Georges County Public Schools	RF272-79770
Rogers Texaco #2	RF321-1368
South Texas Station	RF321-9501
Southwest School Corp.	RF272-81521
Sumner-Eddyville-Miller School	RF272-79583
Sunny Distributors	RF304-6007
Superior Texaco	RF321-1314
Total Transportation, Inc.	RF272-75149
Township of East Norriton, PA	RF272-83546
Transcon Lines	RF304-12358

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, room 1E-234, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, Monday through Friday, between the

hours of 1 p.m. and 5 p.m., except federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: October 31, 1991.

George B. Breznay,

Office of Hearings and Appeals.

Director,

[FR Doc. 91-26932 Filed 11-6-91; 8:45 am]

BILLING CODE 6450-01-M

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-4028-3]

## Acid Rain Advisory Committee "Opt-In" Subcommittee; Open Meeting

**SUMMARY:** In August of 1990, the U.S. Environmental Protection Agency gave notice of the establishment of an Acid Rain Advisory Committee (ARAC) which would provide advice to the Agency on issues related to the development and implementation of the requirements of the acid deposition control title of the Clean Air Act Amendments of 1990.

At its July 15-16 meeting, ARAC established an "Op-In" Subcommittee to provide advice on issues related to the development of regulations under title IV, section 410 of the Clean Air Act Amendments of 1990. This section allows sources which are not affected units under title IV to participate in the allowance market by electing to become affected sources. These sources include certain utility units, industrial units, and process sources which generate sulfur dioxide emissions from non-fossil fuel-fired combustion devices. Sources "opting in" to the allowance system will be allocated allowances by EPA and, like utilities, will be able to bank or trade allowances if they make reductions.

## OPEN MEETING DATES AND ADDITIONAL

**INFORMATION:** Notice is hereby given that the ARAC "Opt-In" Subcommittee will hold its second open meeting on November 19 and 20 from 9 a.m. to 5 p.m. at the Sheraton Hotel, Crystal City, 1800 Jefferson Davis Highway, Arlington, VA (703-486-1111). The meeting will include discussions of baseline data requirements, allowance allocation issues including alternative baselines and applicable emission rates, and permitting and "reduced utilization" for opt-ins.

## INSPECTION OF COMMITTEE DOCUMENTS:

All documents for this meeting including a more detailed meeting agenda will be publicly available in limited numbers at

the meeting. Thereafter, these documents will be available in EPA Air Docket Number A-90-39 in room 1500 of EPA headquarters, 401 M Street SW, Washington, DC. Hours of inspection are 9:30 a.m. to 12 noon and 1:30 to 3:30 p.m., Monday through Friday.

## FOR FURTHER INFORMATION CONTACT:

Concerning the "Opt-In" Subcommittee and its activities, contact the Acid Rain Program Hotline at 617-641-5377.

Dated: November 1, 1991.

Eileen B. Claussen,

Director, Office of Atmospheric and Indoor Air Programs, Office of Air and Radiation.

[FR Doc. 91-26939 Filed 11-6-91; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4027-8]

## Approval and Promulgation of General Permit Revisions for the State of Louisiana

**AGENCY:** U. S. Environmental Protection Agency (EPA).

**ACTION:** Direct final general permit modification.

**SUMMARY:** This notice revises notification requirements for Louisiana Statewide General Permits LAG551000 and LAG556000. These permits authorize discharges to waters of the United States from publicly and privately owned domestic wastewater treatment facilities in the State of Louisiana. See 56 FR 11428 (March 18, 1991); 56 FR 11435 (March 18, 1991). When EPA issued those general permits it inadvertently required facilities to submit multiple application forms. Accordingly it is amending the permits to clarify submission of only the Notice of Intent.

**DATES:** This action becomes effective January 8, 1992 unless adverse or critical comments are received by December 9, 1991.

**ADDRESSES:** Written comments on this action should be addressed to Ms. Wren Stenger, Chief, Municipal Permits Section at the EPA Regional Office listed below. Copies of the relevant documents are available for public inspection during normal business hours at the following locations: US EPA Region 6, Municipal Permits Section (6W-PM), 11th Floor, 1445 Ross Avenue, Dallas, Texas 75202-2733, or Department of Environmental Quality, Water Pollution Control Division, P.O. Box 82215, Baton Rouge, Louisiana 70881-2215. For further information contact: Mr. Tom Hill, Municipal Permits Section (6W-PM), Water Division, US EPA Region 6, 1445 Ross Avenue, Dallas,



Texas 75202-2733 or phone (214) 655-7175 or FTS 255-7175.

EPA is publishing this action without prior proposal because the Agency views these permit revisions as noncontroversial and anticipates no adverse comments. This action will be effective 60 days from the date of this **Federal Register** unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted.

If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will establish a comment period. If no such comments are received, the public is advised that this action will be effective 60 days from the date of publication.

#### Final Action

The existing wording at part II.A.2 of the referenced permits is hereby deleted. The deleted language reads: "2. Any discharger desiring coverage under this General Permit shall submit a (1) Notice of Intent, (2) an EPA Form 3510-1 General Information, (3) and EPA Form 3510-2E Application for Facilities Which Do Not Discharge Process Wastewater (Privately Owned), or Standard Form A, Municipal (EPA Form 7550-22) for Publicly Owned Treatment Works. Dischargers requesting coverage will be notified in writing of authorization to discharge under conditions of this permit."

Part II.A.2 of the permit should read and is hereby changed to read: "Dischargers desiring coverage under this General Permit shall submit a notice of intent that includes the following information.

1. Name of responsible individual and phone number.
  2. Name, description and location of facility.
  3. Type of facility.
  4. Design flow of facility and receiving water.
  5. Any permit numbers assigned to this facility.
  6. Mailing address.
  7. Ownership status, i.e., Federal, State, private or POTW.
  8. Whether facility is located on Indian Lands.
  9. Brief description of business and the relevant SIC codes. Dischargers requesting coverage will be notified in writing of the authorization to discharge under conditions of this permit."
- Nothing in this section should be construed as permitting or allowing or establishing a precedent for any future request for revisions to any permit action. Each request for revisions to a

permit shall be considered separately in light of specific technical, economic and environmental factors and in relation to relevant statutory and regulatory requirements.

Dated: October 25, 1991.

Kenton Kirkpatrick,

*Acting Director, Water Management Division (6W-P).*

[FR Doc. 91-26860 Filed 11-6-91; 8:45 am]

BILLING CODE 6560-50-M

#### FEDERAL MARITIME COMMISSION

##### Agreement(s) Filed; Port Everglades Authority, et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

*Agreement No.:* 224-200076-001.

*Title:* Port Everglades Authority/SeaEscape Terminal Agreement.

*Parties:* Port Everglades Authority; SeaEscape Limited.

*Synopsis:* The Agreement would increase the maximum private vehicle parking fee the port is permitted to charge "Scandinavian Sun" passengers from \$5.00 to \$6.00 per day.

Dated: November 1, 1991.

By Order of the Federal Maritime Commission.

Joseph C. Polking,  
*Secretary.*

[FR Doc. 91-26871 Filed 11-6-91; 8:45 am]

BILLING CODE 6730-01-M

#### FEDERAL RESERVE SYSTEM

##### The Chase Manhattan Corporation; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR

225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 22, 1991.

**A. Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *The Chase Manhattan Corporation*, New York, New York; to acquire, through its subsidiary, Chase Home Mortgage Corporation, Tampa, Florida, certain mortgage servicing rights from Florida Federal Savings Bank, St. Petersburg, Florida, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, November 1, 1991.

Jennifer J. Johnson,

*Associate Secretary of the Board.*

[FR Doc. 91-26872 Filed 11-6-91; 8:45 am]

BILLING CODE 6210-01-F



### Community Bankers, Inc.; Notice of Application to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 29, 1991.

**A. Federal Reserve Bank of Dallas**  
(W. Arthur Tribble, Vice President) 400  
South Akard Street, Dallas, Texas 75222:

1. *Community Bankers, Inc.*, Granbury, Texas; to engage *de novo* in making loans and other extensions of credit pursuant to § 225.25(b)(1) of the Board's Regulation Y. These activities will be conducted in North Central Texas.

Board of Governors of the Federal Reserve System, November 1, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-26873 Filed 11-6-91; 8:45 am]

BILLING CODE 6210-01-F

### James W. Cravens, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 29, 1991.

**A. Federal Reserve Bank of Chicago**  
(David S. Epstein, Vice President) 230  
South LaSalle Street, Chicago, Illinois  
60690:

1. *James W. Cravens*, James P. Cravens, and Mark C. Fisher; to acquire an additional 23.66 percent of the voting shares of Ocheyedan Bancorporation, Ocheyedan, Iowa, for a total of 100 percent, and thereby indirectly acquire Ocheyedan Savings Bank, Ocheyedan, Iowa.

**B. Federal Reserve Bank of St. Louis**  
(Randall C. Sumner, Vice President) 411  
Locust Street, St. Louis, Missouri 63166:

1. *Ben Lovell Cundiff*, Nashville, Tennessee; to retain 25.53 percent, and to acquire an additional 12.05 percent, as well as an option to purchase with a proxy for the right to vote an additional 15 percent of the voting shares of Trigg Bancorp, Inc., Cadiz, Kentucky, for a total of 52.58 percent, and thereby indirectly acquire Trigg County Farmers Bank, Cadiz, Kentucky.

Board of Governors of the Federal Reserve System, November 1, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-26874 Filed 11-6-91; 8:45 am]

BILLING CODE 6210-01-F

### First National Bancorp; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than November 29, 1991.

**A. Federal Reserve Bank of Atlanta**  
(Robert E. Heck, Vice President) 104  
Marietta Street, N.W., Atlanta, Georgia  
30303:

1. *First National Bancorp*, Gainesville, Georgia; to merge with First National Bancshares of Paulding County, Inc., Dallas, Georgia, and thereby indirectly acquire First National Bank of Paulding County, Dallas, Georgia.

Board of Governors of the Federal Reserve System, November 1, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-26875 Filed 11-6-91; 8:45 am]

BILLING CODE 6210-01-F

### FEDERAL TRADE COMMISSION

(File No. 912-3160)

### Nestle Food Co.; Proposed Consent Agreement With Analysis To Aid Public Comment

**AGENCY:** Federal Trade Commission.  
**ACTION:** Proposed Consent Agreement.

**SUMMARY:** In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent



agreement, accepted subject to final Commission approval, would prohibit, among other things, the California-based marketer of Carnation Coffee-mate Liquid from misrepresenting the amount of total fat, saturated fat, or cholesterol in Coffee-mate Liquid or any other milk product or non-dairy substitute, relative to the serving size depicted in its advertisements or promotional materials.

**DATES:** Comments must be received on or before January 6, 1992.

**ADDRESSES:** Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** C. Lee Peeler, FTC/S-4002, Washington, DC 20580. (202) 326-3090.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's rules of practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's rules of practice (16 CFR 4.9(b)(6)(ii)).

**Nestle Food Company, a Corporation; Agreement Containing Consent Order To Cease and Desist**

The Federal Trade Commission having initiated an investigation into certain acts and practices of Nestle Food Company, formerly known as Carnation Company, a Delaware corporation, hereinafter sometimes referred to as proposed respondent, and it now appearing that proposed respondent and Nestle Beverage Company (hereinafter collectively referred to as "the companies"), both of which are wholly owned subsidiaries of Nestle Holdings, Inc., are willing to enter into an agreement containing an order to cease and desist from the use of the acts or practices being investigated.

It is hereby agreed by and between Nestle Food Company and Nestle Beverage Company, by their duly authorized officers, and their attorney, and counsel for the Federal Trade Commission that:

1. The companies are corporations organized, existing and doing business under and by virtue of the laws of the state of Delaware, with the offices of

Nestle Food Company and its principal place of business located at 800 North Brand Boulevard, Glendale, California 91203, and the offices of Nestle Beverage Company and its principal place of business located at 345 Spear Street, San Francisco, California 94105.

2. The companies admit all the jurisdictional facts set forth in the draft complaint here attached.

3. The companies waive: (a) Any procedural steps;

(b) The requirement that the Commission's decision contain a statement of finding of fact and conclusion of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this Agreement; and

(d) Any claim under the Equal Access to Justice Act.

4. This Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission, it, together with the draft complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information with respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Agreement and so notify the companies, in which event it will take such issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This Agreement is for settlement purposes only and does not constitute an admission by the companies that the law has been violated as alleged in the attached draft complaint, or that the facts as alleged in the attached draft complaint, other than the jurisdictional facts, are true.

6. The Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to the companies: (1) Issue its complaint corresponding in form and substance with the draft complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding; and (2) make information public with respect thereto. When so entered, the order to cease and desist shall have the same force and effect as other orders and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service.

Delivery by the U.S. Postal Service of the complaint and decision containing the signed order to the companies' addresses, as stated in this Agreement, shall constitute service. The complaint may be used in constructing the terms of the order, and no agreement, understanding, representations, or interpretation not contained in the order or this Agreement may be used to vary or contradict the terms of the order.

7. The companies have read the proposed complaint and order contemplated hereby. They understand that once the order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the order. The companies further understand that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

**Order**

*Definitions*

For purposes of this Order, the term "milk product" shall mean any product for which a federal standard of identity has been established under 21 CFR part 131 as currently in effect as of the date of this Order.

For purposes of this Order, the term "non-dairy substitute" shall mean any product which is commonly used as a substitute for a milk product which, for purposes of this Order, shall include but not be limited to any non-dairy creamer.

**I**

It is ordered that Nestle Food Company, formerly known as Carnation Company, and Nestle Beverage Company (collectively "the companies"), their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any food, in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Misrepresenting in any manner, directly or by implication, through numerical or descriptive terms or any other means, the absolute or comparative amount of total fat, saturated fat or cholesterol in any milk product or any non-dairy substitute; and

B. Misrepresenting in any manner, directly or by implication, through numerical or descriptive terms or any other means, the existence or amount of total fat, saturated fat or cholesterol in



any milk product or non-dairy substitute relative to the serving size or amount customarily consumed for any particular use being advertised or promoted.

*Provided, however,* That nothing in provisions A and B above shall prohibit any representation as to the amount of total fat, saturated fat or cholesterol in any milk product or non-dairy substitute if such representation is specifically permitted in labeling, for the serving size advertised or promoted for such product, by regulations promulgated by the U.S. Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act.

## II

This Order shall not apply to an unaffiliated purchaser of the assets of the dairy currently owned by Nestle Food Company and located in Phoenix, Arizona, provided that the sale of such dairy's assets are conducted in a manner consistent in all material respects with the description and terms of that sale as set forth in the attached letter, dated October 16, 1991, from Nestle Food Company to Federal Trade Commission staff, and provided further that Nestle Food Company shall remain responsible under the terms of this Order for any representation made, as covered by Part I of this Order, for any milk product or non-dairy substitute marketed under a trademark of Nestle Food Company.

## III

*It is further ordered* that for three (3) years after the last date of dissemination of the representation, the companies, or their successors and assigns, shall maintain and, upon request, make available to the Federal Trade Commission for inspection and copying copies of:

A. All materials that were relied upon by the companies in disseminating any representation covered by this Order; and

B. All test reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question any representation that is covered by this Order.

## IV

*It is further ordered* that the companies shall notify the Commission at least thirty (30) days prior to any proposed change in the companies, such as dissolution, assignment or sale, resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the companies which may

affect compliance obligations arising out of this Order.

## V

*It is further ordered* that the companies shall, within thirty (30) days after service upon them of this Order, distribute a copy of this Order to each of their operating divisions, to each of their managerial employees, and to each of their officers, agents, representatives, or employees engaged in the preparation or placement of advertising or other material covered by this Order.

## VI

*It is further ordered* that the companies shall, within sixty (60) days after service of this Order and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

## Attachment A

October 16, 1991

Michelle Rusk, Esq.,

Anne Maher, Esq.

Federal Trade Commission, Washington,  
D.C. 20680

Dear Ms. Rush and Ms. Maher:

I am representing Nestle Food Company in the sale of the assets of its Phoenix dairy operation. The following is some information about the proposed sale of the dairy which we believe is relevant to excluding it from the proposed Order.

First, and perhaps most importantly, Nestle Food Company is only selling assets of the dairy located in Phoenix, Arizona to an unaffiliated entity. Those assets are valued at less than 1% of the total value of the Nestle Food Company.

Secondly, to assist in promoting a smooth transition of the sale of the assets by the Nestle Food Company to the unaffiliated entity, Nestle Food Company will be licensing the new owner to use certain of its trademarks for a limited period of time. Under the terms of the trademark license, Nestle will have the ability to reasonably control the labeling and advertising of products that display a Nestle trademark.

Thirdly, the dairy operation is a regional stand-alone business. It manufactures milk, sour cream, cottage cheese and the like. The dairy does not manufacture any of the products promoted in the alleged violative advertising.

Fourthly, while a minority of the shareholders of the proposed purchaser include a present and a former Carnation employee, none of the shareholders had any responsibility or involvement in the alleged violative advertising.

Lastly, we wish to stress that the sale of the assets of the dairy is purely the result of a business decision by Nestle Food Company to discontinue its involvement with this type of business operation, and is not motivated in any way by an attempt to circumvent the Order.

Yours very truly,

Mark Evans

## Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Nestle Food Company ("NFC"), formerly known as Carnation Company.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter concerns claims made by NFC in its advertising for Carnation Coffee-mate Liquid ("CML"), a liquid non-dairy creamer.

The Commission's complaint in this matter charges NFC with engaging in deceptive and unfair practices in connection with the advertising of CML. According to the complaint, NFC's advertisements for CML represented that CML is a low-fat product when consumed in an amount normal for use on cereal, on fruit or in cooking—uses that were promoted in CML advertising. This representation is alleged to be false and misleading. At the serving size commonly consumed for these uses, CML exceeds accepted standards for a low-fat food.

The complaint also alleges that NFC's advertisements for CML represented that CML is lower in fat than other foods, such as whole milk or low-fat (2%) milk, for which it might be used as a substitute on cereal, on fruit or in cooking. This representation is also alleged to be false and misleading. CML has nearly twice the amount of fat per serving as whole milk and nearly four times the amount of fat per serving as low-fat (2%) milk.

The consent order contains provisions designed to remedy the violations charged and to prevent both NFC and Nestle Beverage Company ("NBC"), the company currently responsible for marketing of CML, from engaging in similar deceptive and unfair acts and practices in the future. Both NFC and NBC are wholly owned subsidiaries of Nestle Holdings, Inc.

Part I of the order prohibits NFC and NBC from misrepresenting the absolute or comparative amount of total fat, saturated fat or cholesterol in CML or in any other milk product or non-dairy substitute. A milk product is defined as



any product for which a standard of identity has been established by the Food and Drug Administration under 21 CFR part 131. A non-dairy substitute is defined, for purposes of the order, as a product which is commonly used as a substitute for a milk product. Part I also prohibits NFC and NBC specifically from misrepresenting the amount of total fat, saturated fat or cholesterol in CML or any other milk product or non-dairy substitute, relative to the serving size being advertised. Finally, Part I provides that the order shall not prohibit representations as to the amount of total fat, saturated fat or cholesterol in a milk product or non-dairy substitute, provided such representation complies with regulations of the Food and Drug Administration for the serving size being depicted in the advertising.

Part II of the order exempts from coverage the unaffiliated purchaser of the assets of a dairy located in Phoenix, Arizona and currently owned by NFC, provided the sale is conducted in a manner consistent with representations of NFC. A letter detailing these representations is attached to the order. Under this provision, NFC will continue to be responsible for representations made for any product marketed under a trademark of NFC.

Part III requires NFC and NBC to maintain copies of all materials relating to advertisements covered by the order and all documents relating to substantiation of advertising claims covered by the order.

Part IV requires NFC and NBC to notify the Commission of any changes in corporate structure that might affect compliance with the order.

Part V requires NFC and NBC to distribute copies of the order to certain company officials and employees and certain other representatives and agents of the two companies.

Part VI requires NFC and NBC to file with the Commission one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.

Donald S. Clark,  
Secretary.

[FR Doc. 91-26927 Filed 11-6-91; 8:45 am]  
BILLING CODE 6750-01-M

[File No. 902-3006]

# **Pinkerton Tobacco Co.; Proposed Consent Agreement With Analysis To Aid Public Comment**

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

**SUMMARY:** In settlement of alleged violations of federal law prohibiting unfair acts and practices, unfair methods of competition, and the Comprehensive Smokeless Tobacco Health Education Act of 1986, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, the Virginia-based company from advertising any smokeless tobacco product on any broadcast medium, including television, in connection with the broadcast of any Pinkerton-sponsored event, and would require the respondent to distribute a copy of the order to each operating division, manager, officer, agent, or employee engaged in advertising or sponsorship activities, the production of sponsored events, or other sales materials.

**DATES:** Comments must be received on or before January 6, 1992.

**ADDRESSES:** Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW, Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Judy Wilkenfeld, FTC/4002, Washington, DC 20580. (202) 326-3150.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's rules of practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's rules of practice (16 CFR 4.9(b)(6)(ii)).

## **The Pinkerton Tobacco Company, a Corporation; Agreement Containing Consent Order To Cease and Desist**

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Pinkerton Tobacco Company ("Pinkerton"), a corporation, hereinafter referred to as proposed respondent or respondent, and it now appearing that

proposed respondent is willing to enter into an agreement containing an order to cease and desist from the use of certain acts and practices being investigated.

It is hereby agreed by and between the Pinkerton Tobacco Company, by its duly authorized officer and its attorneys, and counsel for the Federal Trade Commission that:

1. Pinkerton is a corporation organized, existing, and doing business under and by virtue of the law of the State of Delaware. Pinkerton's office and principal place of business is located at 6630 W. Broad Street, Post Office Box 1158, Richmond, VA 23230.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint here attached.

4. Proposed respondent waives:

- a. Any further procedural steps;
- b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;
- c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and
- d. All claims under the Equal Access to Justice Act.

5. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft of complaint here attached.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's rules, the Commission may, without further notice to the proposed respondent, (a) issue its complaint and order to cease and desist in disposition of the proceeding and (b) make information public in respect



thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

8. Proposed respondent has read the proposed complaint and order contemplated hereby. Proposed respondent understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the order. Proposed respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

#### Order

For the purposes of this Order, the following definitions apply:

1. The term "event" means any type of gathering for public entertainment with or without an audience, including, but not limited to, any athletic or sporting activity (such as tractor pulls and monster truck events, racing, rodeo, wrestling, or fishing) or musical, artistic, or nightclub activity.

2. The term "broadcast" refers to appearances on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

3. The term "smokeless tobacco product" measures smokeless tobacco as defined in section 9(1) of the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. 4408(1).

#### Part I

*It is ordered* that respondent the Pinkerton Tobacco Company, a corporation, and its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with a broadcast of any event which it sponsors, do forthwith cease and desist from advertising any smokeless tobacco product on any medium of electronic

communications subject to the jurisdiction of the Federal Communications Commission;

*Provided however*, that in connection with a broadcast of a sponsored event, nothing in this Order shall prohibit:

A. The use of a brand name of a smokeless tobacco product as the name of the sponsored event provided that the logo, selling message, color, or design feature of the product or its packaging is not used, however:

1. The brand name as qualified above may be used as part of a program identifier at the beginning or end of a program or before or after a commercial break;

2. The brand name as qualified above may be used within advertising by the broadcaster for the program so long as the advertising is not directly or indirectly placed or made by respondent;

B. Any incidental or de minimis broadcast of a brand name, logo, selling message, or event name so long as the brand name, logo, selling message or event name does not appear:

1. On signage in an area on which cameras routinely focus during an event (e.g., the starting and finishing line in a truck or tractor pull);

2. On signage on competing vehicles or other event equipment upon which cameras routinely focus (e.g., the weighted sled pulled during a truck or tractor event); or

3. On clothing of event officials, commentators, competitors, or participants, if provided to them directly or indirectly by respondent.

*Provided further* that this Order shall not cover:

C. The first broadcast of an event which had never before been broadcast, if respondent could not have reasonably foreseen the broadcast of this type of event; or

D. Any films or video tapes of any event in existence at the time the parties enter this agreement over which respondent has no control, provided however, that respondent shall send a copy of this Order to each and every entity that it knows possesses such a film or tape.

#### Part II

*It is further ordered* that within thirty (30) days after service of this Order, respondent, its successors and assigns, shall distribute a copy of this Order to each of its operating divisions, to each of its managerial employees, and to each of its officers, agents, representatives, or employees engaged in the preparation or placement of advertising, sponsorship activities, production of sponsored events, or other sales material covered

by this Order and shall secure from each such person a signed statement acknowledging receipt of this Order.

#### Part III

*It is further ordered* that respondent, its successors and assigns, for three (3) years after the date of entry of this Order, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying all business records, including, but not limited to, sponsorship agreements, trademark license agreements, and films or video tapes of sponsored events covered by part I of this Order.

#### Part IV

*It is further ordered* that respondent, its successors and assigns, shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of successor corporations, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of the Order.

#### Part V

*It is further ordered* that respondent, its successors and assigns, shall, within sixty (60) days after service upon it of this Order and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with the requirements of this Order.

#### Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to public comment, to a proposed consent order from the Pinkerton Tobacco Company ("Pinkerton").

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter concerns certain Pinkerton advertising activities in connection with sponsored events that have appeared on television. The Commission's complaint charges that Pinkerton has advertised its smokeless tobacco products on television in connection with company-sponsored



events and that such advertising violates the broadcast advertising ban contained within the Comprehensive Smokeless Tobacco Health and Education Act of 1986 ("the Smokeless Tobacco Act"). In particular, the complaint charges that Pinkerton has sponsored certain events, including the "Red Man Pulling Series," a series of truck and tractor events. The complaint further alleges that Pinkerton allowed these events to be taped for television broadcast and that the events have appeared on television. In addition, the complaint charges that Pinkerton paid for the display of its smokeless tobacco product brand names, logos, and selling messages in connection with such events. According to the complaint, these brand names, logos, and selling messages have appeared in the following places:

The pulling sleds, which competing vehicles pull, contain flags and other signage bearing smokeless tobacco brand names, logos, and selling messages, including the name "Red Man," the Red Man Indian head logo, and the selling messages, "Chewing Tobacco" or "America's Best Chew." Such sleds appear prominently throughout the broadcasts.

Banners, line markers, and other signage, bearing the Red Man name and logo, appear during the broadcasts.

Event workers, competitors, and other participants sometimes appear on screen wearing hats and uniforms containing the Red Man brand name, logo, or selling messages.

Television program identifiers, which appear at the beginning or the end or before or after commercial breaks, include the Red Man Indian head logo.

The complaint further charges that such activities constitute "advertising" on television in violation of the broadcast advertising ban contained within the Smokeless Tobacco Act.

The consent order contains provisions designed to remedy the violations charged and to prevent respondent from engaging in similar activities in the future. In particular, part I prohibits Pinkerton from advertising any smokeless tobacco product on any broadcast medium, including television, in connection with the broadcast of any Pinkerton-sponsored event. Part I provides limited exceptions to the foregoing prohibition. Specifically, the order does not prohibit Pinkerton from using a brand name as the name of an event, so long as no logo, selling message, color, or design feature of a product or its packaging is used (this restricted use of the brand name is referred to hereinafter as "the qualified brand name"). In addition, the qualified

brand name may otherwise be used only as a television program identifier (e.g., "The Red Man Series") appearing at the beginning and end and before and after commercial breaks, and in advertisements for upcoming programs (e.g., "our fall line-up will include 'The Red Man Series'") placed by the broadcaster.

In addition, Part I sets forth that incidental or de minimis appearances of a brand name, logo, selling message, or qualified brand name (see above) would not be prohibited. The order provides, however, that certain appearances would not be deemed de minimis. For example, the order specifically provides that signage containing a brand name, logo, selling message, or qualified brand name that appears in areas where cameras routinely focus, such as a starting or finishing line, would not be incidental or de minimis. Similar signage on competing vehicles or equipment or brand names, logos, selling messages, or qualified brand names appearing on clothing of event participants also would not be deemed de minimis.

Finally, part I provides that Pinkerton would not be liable under the order for the first broadcast of an event that never before has been broadcast or for any tapes or films in existence at the date of the agreement over which Pinkerton has no control; however, Pinkerton is required to notify any person or entity that it knows possesses such tapes or films that this order has been issued.

Part II requires respondent to distribute a copy of the order to each operating division, each managerial employee, and each officer, agent, representative, or employee engaged in advertising or sponsorship activities, the production of sponsored events, or other sales materials. Each such person must sign a statement acknowledging receipt of the order.

Part III requires respondent to maintain all business records, including sponsorship agreements, trademark license agreements, and films or video tapes of sponsored events for three years.

Part IV of the order requires respondent to notify the Commission prior to any change in the corporation that may affect compliance obligations arising out of the order.

Part V of the order requires respondent to file compliance reports with the Commission.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of

the agreement and proposed order, or to modify in any way their terms.

Donald S. Clark,  
Secretary.

[FR Doc. 91-26928 Filed 11-6-91; 8:45 am]  
BILLING CODE 6750-01-M

[File No. 882-3214]

### St. Ives Laboratories, Inc.; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

**SUMMARY:** In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, a California company from representing that its skin cream or any other non-prescription skin cream is, contains, or has the same wrinkle-removing effect as the prescription drug tretinoin or from representing that its cosmetic products are, contain, or have the same effect as another manufacturers' prescription drug. Respondent would also be prohibited from representing that its skin product is new or that it helps reduce the visible signs of aging. In addition, respondent would be required to pay \$100,000 to be deposited into the United States Treasury.

**DATES:** Comments must be received on or before January 6, 1992.

**ADDRESSES:** Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Pamela Wood, Boston Regional Office, Federal Trade Commission, 10 Causeway St., room 1184, Boston, Mass. 02222-1073. (617) 565-7240.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's rules of practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's rules of practice (16 CFR 4.9(b)(6)(ii)).



**St. Ives Laboratories, Inc., a Corporation;  
Agreement Containing Consent Order  
To Cease and Desist**

The Federal Trade Commission having initiated an investigation of certain acts and practices of St. Ives Laboratories, Inc., and its now appearing that St. Ives Laboratories, Inc., hereinafter sometimes referred to as respondent, is willing to enter into an agreement containing an order to cease and desist from the use of the acts and practices being investigated;

*It is hereby agreed by and between St. Ives Laboratories, Inc., and its counsel, and counsel for the Federal Trade Commission that:*

1. St. Ives Laboratories, Inc., hereinafter referred to as the corporation, is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business at 8944 Mason Avenue, Chatsworth, California 91311.

2. Respondent admits all the jurisdictional facts set forth in the draft of the complaint here attached.

3. Respondent waives:

a. Any further procedural steps;  
b. The requirement that the Commission's decision contain a statement of the findings of fact and conclusions of law;  
c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement;

d. All rights under the Equal Access to Justice Act.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. The agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in the draft of complaint here attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant

to the provisions of § 2.34 of the Commission's rules, the Commission may, without further notice to respondent, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to respondent's address as stated in this agreement shall constitute service. Respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Respondent has read the proposed complaint and order contemplated hereby. It understands that once the order has been issued, it will be required to file one or more compliance reports showing that it fully complied with the order. Respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

#### Order

#### I

*It is ordered* that respondent St. Ives Laboratories, Inc., a corporation, its successors and assigns, officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, packaging, advertising, promoting, offering for sale, selling or distributing of "ST. IVES A\* Retinyl Palmitate Treatment Cream" (hereinafter referred to as "St. Ives A\*") or any other non-prescription skin cream in or affecting commerce as "commerce" is defined in section 4 of the Federal Trade Commission Act, 15 U.S.C. 44, do forthwith cease and desist from representing in any manner, contrary to fact, directly or by implication, that such product is, contains, or has the same wrinkle-removing effect as the prescription drug tretinoin (currently known as "Retin-A"). As used in this paragraph, the term "representing" shall

not apply to the act, without more, of manufacturing products for third parties.

#### II

*It is further ordered* that respondent, its successors and assigns, and its officers, agents, representatives, and employee, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, packaging, advertising, promoting, offering for sale, selling or distributing of ST. IVES A\* or any successor product, do forthwith cease and desist from creating a direct visual association between the terms "RETINYL" or "RETINOL" or "A" in such a way that the term "RETINYL" or "RETINOL" immediately precedes the term "A", through the use of any design features (including without limitation spacing, letter size, color or capitalization).

#### III

*It is further ordered* that respondent, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, packaging, advertising, promoting, offering for sale, selling or distributing of ST. IVES A\* or any successor product where the words "RETINYL" or "RETINOL" are prominently featured on the package, in or affecting commerce as "commerce" is defined in section 4 of the Federal Trade Commission Act, do forthwith cease and desist from claiming or representing, directly or by implication, that such product is "new," that it is a "breakthrough" or "advance" in skin care, or that it "helps reduce the visible signs of aging."

#### IV

*It is further ordered* that respondent, its successors and assigns, officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, packaging, advertising, promoting, offering for sale, selling, or distributing of any product which is solely a cosmetic in or affecting commerce, as "cosmetic" and "commerce" are defined in sections 4 and 15 of the Federal Trade Commission Act, 15 U.S.C. 44 and 55, do forthwith cease and desist from representing, directly or by implication, contrary to fact, that its cosmetic product is, contains, or has the same effect as another manufacturer's prescription drug. As used in this paragraph, the term



"representing" shall not apply to the act, without more, of manufacturing products for third parties.

#### V

It is further ordered that respondent, its successors and assigns, officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, do forthwith cease and desist from distributing or selling any package of ST. IVES A\* that displays the labeling or packaging shown in Exhibit A.<sup>1</sup>

#### VI

It is further ordered that respondent and its successors and assigns shall deliver to the Federal Trade Commission a certified check for One Hundred Thousand Dollars (\$100,000) payable to the "Treasurer of the United States" within ten calendar days of written notice of this order. This amount shall be deposited into the United States Treasury. No portion of the payment as herein provided shall be deemed a payment of any fine, penalty or punitive assessment.

#### VII

It is further ordered that respondent and its successors and assigns shall distribute a copy of this order to all present and future officers, to each of its operating divisions, and to each and every employee involved in managerial or marketing activities in connection with the sale of cosmetics in any business organization owned, directed or controlled, directly or indirectly, by respondent for a period of five (5) years from the date of entry of this order.

#### VIII

It is further ordered that for a period of five (5) years from the date of entry of this order, respondent and its successors and assigns shall notify the Commission at least thirty (30) days prior to any proposed change such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

#### IX

It is further ordered that respondent and its successors and assigns shall, within sixty (60) days after service of this order, file with the Commission a report, in writing, setting forth in detail

the manner and form in which it has complied with this order.

#### Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from St. Ives Laboratories, Inc., a corporation (the "respondent"). Under this agreement, the respondent will cease and desist from making certain representations about certain of its products, and will make a payment of \$100,000.00 to the United States Treasury.

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action, or make final the proposed order contained in the agreement.

This matter concerns advertisements for an over-the-counter facial skin cream currently known as St. Ives A Retinyl Palmitate Cosmetic Treatment Cream ("St. Ives A"). The Complaint accompanying the proposed consent order alleges that, in connection with promoting this cream, the respondent engaged in deceptive acts and practices in violation of section 5 of the Federal Trade Commission Act and that the respondent disseminated deceptive advertisements in violation of section 12 of the Federal Trade Commission Act. According to the Complaint, the respondent represented, directly or by implication, that its skin cream was the same as, contained, or had the same wrinkle-removing effect as, the prescription drug tretinoin (currently being marketed under the trade name "Retin-A").

The consent order contains provisions designed to prevent the respondents from engaging in similar allegedly illegal acts and practices in the future.

Specifically, part I of the order prohibits the respondents from representing that St. Ives A is, contains, or has the same wrinkle-removing effect as the prescription drug tretinoin.

Part II of the order prohibits the respondent, in connection with the marketing of St. Ives A or any successor product, from creating a direct visual association, through the use of any design features, between the terms, "RETINYL" or "RETINOL" and "A" in such a way either of the first two terms immediately precedes the term "A."

Part III of the order prohibits the respondent from representing that St. Ives A or any successor product is "new," that it is a "breakthrough" or "advance" in skin care, or that it "helps reduce the visible signs of aging."

Part IV of the order prohibits the respondent from representing, contrary to fact, that any of its products which is solely a cosmetic is, contains, or has the same effect as another manufacturer's prescription drug.

Part V of the order prohibits the respondent from marketing St. Ives A in the packaging shown in Exhibit A to the Order, which depicts the two different styles of packaging used by St. Ives between April and December, 1988.

Part VI of the order provides that the respondent shall deliver a certified check for \$100,000.00 to the Federal Trade Commission, payable to the "Treasurer of the United States." The funds shall be deposited in the United States Treasury.

Part VII of the order requires the respondent to distribute a copy of the order to its officers and employees involved in managerial or marketing activities in connection with the sale of cosmetics.

Part VIII of the order requires the respondent, for a period of five years from the date of the order, to notify the Federal Trade Commission of any changes in the corporation which may affect compliance obligations.

Part IX of the order requires the respondent to file a report with the Commission within sixty days after service of the order detailing the manner and form in which it has complied with the order.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order, or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 91-26929 Filed 11-6-91; 8:45 am]

BILLING CODE 6750-01-M

#### GENERAL SERVICES ADMINISTRATION

#### Information Collection Activities Under Office of Management and Budget Review

**AGENCY:** Office of Acquisition Policy (VM), GSA.

**SUMMARY:** The GSA hereby gives notice under the Paperwork Reduction Act of 1980 that it is requesting the Office of Management and Budget (OMB) to

<sup>1</sup> Copies are available from the Commission, Public Reference Branch, H-130, 6th & Pa. Ave., NW., Washington, DC 20580.



approve a new information collection, GSAR: Revisions are intended to simplify, clarify, and reduce data submission requirements. Approval is sought for limited test usage of revised DSMD. If the pilot test is successful, the revision will replace 3090-0235, Multiple Awards Schedules.

**ADDRESSES:** Send comments to Bruce McConnell, GSA Desk Officer, room 3235, NEO, Washington, DC 20503, and to Mary L. Cunningham, GSA Clearance Officer, General Services Administration (CAIR), 18th & F Street NW., Washington, DC 20405.

#### Annual Reporting Burden

*Respondents:* 300; *Annual Responses:* 1; *Average Hours per Response:* 15.00; *Burden Hours:* 4,500.

**FOR FURTHER INFORMATION CONTACT:** Les Davison, (202) 501-4768. Copy of Proposal: May be obtained from the Information Collection Management Branch (CAIR), 7102, GSA Building, 18th & F St. NW., Washington, DC 20405, by telephoning (202) 501-2691, or by faxing your request to (202) 501-2727.

Dated: October 31, 1991.

Emily C. Karam,

Director, Information Management Division.

[FR Doc. 91-26887 Filed 11-6-91; 8:45 am]

BILLING CODE 6820-61-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Additions to Senior Executive Service Performance Review Board Membership

Title 5, U.S.C. 4314(c)(4), of the Civil Service Reform Act of 1978, Public Law 95-484, requires that the appointment of Performance Review Board members be published in the Federal Register.

On September 27, 1991, the Department of Health and Human Services' PRB membership was published in the Federal Register. The

following members are hereby added to that membership:

Charles R. Gillum,

Bryan B. Mitchell.

Date: October 31, 1991.

Thomas S. McFee,

Assistant Secretary for Personnel Administration.

[FR Doc. 91-23817 Filed 11-6-91; 8:45 am]

BILLING CODE 4110-60-M

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of Administration

[Docket No. N-91-3341]

#### Submission of Proposed Information Collection to OMB

**AGENCY:** Office of Administration, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Jennifer Main, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708-0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

**SUPPLEMENTARY INFORMATION:** The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

**Authority:** Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d)

Dated: October 28, 1991.

John T. Murphy,

Director, Information Resources Management Policy and Management Division.

#### Notice of Submission of Proposed Information Collection to OMB

**Proposal:** Mortgagee's Certification and Application/Monthly Summary of Assistance Payments due under section 235(b), 235(j), or 235(i) or of interest Reduction Payments due under section 236.

**Office:** Housing.

**Description of the Need for the Information and its Proposed Use:** This information is needed because all assistance payments disbursed under this program must be monitored by HUD. The form, Monthly Summary of Assistance Payments (HUD-300), is submitted by the mortgagees with the form, Mortgagee's Certification and Application or Interest Reduction Payments (HUD-93102).

**Form Number:** HUD-93102 and HUD-300.

**Respondents:** Businesses or Other For-Profit.

**Frequency of Submission:** Monthly.

**Reporting Burden:**

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Form HUD-93102.....	962		18		.25		4,329
Form HUD-300.....	962		13.746		1		13,224



Total Estimated Burden Hours: 17,553.

Status: Reinstatement.

Contact: Florence B. Brooks, HUD,  
(202) 708-1719, Jennifer Maine, OMB,  
(202) 395-6880.

Dated: October 28, 1991.

[FR Doc. 91-26858 Filed 11-6-91; 8:45 am]

BILLING CODE 4210-01-M

## DEPARTMENT OF THE INTERIOR

### Joint Tribal/BIA/DOI Advisory Task Force on Bureau of Indian Affairs Reorganization, Public Meeting

AGENCY: Department of the Interior.

ACTION: Notice of meeting.

**SUMMARY:** Pursuant to Public Law 101-512, the Office of the Assistant Secretary—Indian Affairs is announcing the forthcoming meeting of the Joint Tribal/BIA/DOI Advisory Task Force on Bureau of Indian Affairs Reorganization (Task Force).

**DATES:** November 19, 20, and 21, 1991; 9 a.m. to 5:30 p.m. daily; the Hyatt Islandia, 1441 Quivira Road, San Diego, California. The meeting of the Task Force is open to the public.

**FOR FURTHER INFORMATION CONTACT:** Veronica L. Murdock, Designated Federal Officer, Office of the Assistant Secretary—Indian Affairs, MS 4140, 1849 C Street NW., Washington, DC, 20240; Telephone number (202) 208-4173.

**SUPPLEMENTARY INFORMATION:** The Joint Tribal/BIA/DOI Advisory Task Force on Bureau of Indian Affairs Reorganization will discuss the Agency and Area Office organizational structures proposed by tribal leaders from each Area and will begin an analysis of the Central Office structure, functions, responsibilities, and authorities that need to be changed based on the Agency and Area Office proposals. The Budget Process, Delegations of Authority, Central Office Structure, Report Writing, and Economic Development Work Groups will continue work to present the results of their analyses as recommendations for Task Force action. Time for comments from the public on Task Force issues will be available during the meeting.

Dated: November 1, 1991.

Eddie F. Brown,

Assistant Secretary—Indian Affairs.

[FR Doc. 91-26822 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-02-M

## Bureau of Land Management

[MT-921-08-4120-11; NDM 80299]

### Coal Leases Exploration Licenses, North Dakota

AGENCY: Bureau of Land Management, Montana State Office, Interior.

ACTION: Notice of invitation coal exploration license application NDM 80299.

Members of the public are hereby invited to participate with The Coteau Properties Company in a program for the exploration of coal deposits owned by the United States of America in the following described lands located in Mercer County, North Dakota:

T. 145 N., R. 86 W., 5th P.M.  
Sec. 6: Lots 3, 4, 5, SE $\frac{1}{4}$ NW $\frac{1}{4}$ ,  
Sec. 8: NW $\frac{1}{4}$ NW $\frac{1}{4}$ , SE $\frac{1}{4}$ NW $\frac{1}{4}$ ,  
SE $\frac{1}{4}$ SW $\frac{1}{4}$ , NE $\frac{1}{4}$ SE $\frac{1}{4}$ , S $\frac{1}{2}$ SE $\frac{1}{4}$   
Sec. 18: E $\frac{1}{2}$   
T. 145 N., R. 88 W., 5th P.M.  
Sec. 4: Lot 4, SW $\frac{1}{4}$ NW $\frac{1}{4}$ , SW $\frac{1}{4}$   
Sec. 22: All  
1,591.70 acres—Mercer County.

Any party electing to participate in this exploration program shall notify, in writing, both the State Director, Bureau of Land Management, P.O. Box 36600, Billings, Montana 59107; and The Coteau Properties Company, P.O. Box 1089, Beulah, North Dakota 58523. Such written notice must refer to serial number NDM 80299 and be received no later than 30 calendar days after publication of this notice in the *Federal Register* or 10 calendar days after the last publication of this notice in the Beulah Beacon newspaper, whichever is later. This notice will be published once a week for 2 consecutive weeks.

The proposed exploration program is fully described and will be conducted pursuant to an exploration plan to be approved by the Bureau of Land Management. Copies of the exploration plan as submitted by The Coteau Properties Company is available for public inspection at the Bureau of Land Management, Montana State Office, Granite Tower Building, 222 North 32nd Street, Billings, Montana during regular business hours (9 a.m. to 4 p.m.) Monday through Friday.

Dated: October 29, 1991.

Francis R. Cherry, Jr.,

Associate State Director.

[FR Doc. 91-26894 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-DN-M

[WY-920-41-5700; WYW108854]

### Proposed Reinstatement of Terminated Oil and Gas Lease

Pursuant to the provisions of Public Law 97-451, 96 Stat. 2462-2466, and Regulation 43 CFR 3108.2-3(a) and (b)(1), a petition for reinstatement of oil and gas lease WYW108854 for lands in Sweetwater County, Wyoming, was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$5 per acre, or fraction thereof, per year and 16% percent, respectively.

The lessee has paid the required \$500 administrative fee and \$125 to reimburse the Department for the cost of this *Federal Register* notice.

The lessee has met all the requirements for reinstatement of the lease as set out in section 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease WYW108854 effective May 1, 1991, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Pamela J. Lewis,

Supervisory Land Law Examiner.

[FR Doc. 91-26895 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-22-M

[WY-920-41-5700; WYW108862]

### Proposed Reinstatement of Terminated Oil and Gas Lease

Pursuant to the provisions of Public Law 97-451, 96 Stat. 2462-2466, and Regulation 43 CFR 3108.2-3(a) and (b)(1), a petition for reinstatement of oil and gas lease WYW108862 for lands in Sweetwater County, Wyoming, was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$5 per acre, or fraction thereof, per year and 16% percent, respectively.

The lessee has paid the required \$500 administrative fee and \$125 to reimburse the Department for the cost of this *Federal Register* notice.

The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease WYW108862 effective May 1, 1991, subject to the original terms and



conditions of the lease and the increased rental and royalty rates cited above.

Pamela J. Lewis,  
Supervisory Land Law Examiner.

[FR Doc. 91-26896 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-22-M

[ID-943-4212-16; IDI-7309]

### Order Providing for Opening of Public Land; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Opening order.

**SUMMARY:** This order revokes the suitable classification for the lands in a relinquished allowed desert entry and opens them to the land, mining and mineral leasing laws.

**EFFECTIVE DATE:** December 9, 1991.

**FOR FURTHER INFORMATION CONTACT:** Larry R. Lievsay, BLM, Idaho State Office, 3380 Americana Terrace, Boise, Idaho 83706, 208-384-3166.

1. The suitable classification for desert land entry on the following described land is hereby revoked.

#### Boise Meridian, Idaho

T. 9 S., R. 21 E.,  
sec. 24, SE $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
sec. 25, NE $\frac{1}{4}$ NE $\frac{1}{4}$ .  
T. 9 S., R. 22 E.,  
sec. 19, lot 4 and SE $\frac{1}{4}$ SW $\frac{1}{4}$ ;  
sec. 30, lot 1 and NE $\frac{1}{4}$ NW $\frac{1}{4}$ .

The area described contains 246.36 acres in Minidoka County.

2. At 9 a.m. on December 9, 1991, the lands described in paragraph one will be opened to the operation of the land laws generally, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid applications received at or prior to 9 a.m. on December 9, 1991, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

3. At 9 a.m. on December 9, 1991, the lands described in paragraph one will be opened to location and entry under the United States mining laws and to applications and offers under the mineral leasing laws. Appropriation of any of the lands described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38, shall vest no rights against the United States. Acts required to establish a

location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: October 29, 1991.

Delmar D. Vail,  
State Director.

[FR Doc. 91-26897 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-GG-M

[G-010-G1-0120-4212-13; NMNM 32341]

### Order Providing for Opening of Public Land; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

**SUMMARY:** This order opens certain land received in an exchange with the Navajo Tribe of Indians to the public land laws, but not the mining and mineral leasing laws because the mineral estate was not reconveyed to the United States. The remaining land received in the exchange is withdrawn by Public Law 100-225 dated December 31, 1987, and shall be managed in accordance with all laws, rules, and regulations applicable to that law.

**FOR FURTHER INFORMATION CONTACT:** Rio Puerco Resource Area Manager, 435 Montano NE, Albuquerque, New Mexico 87107.

**SUPPLEMENTARY INFORMATION:** In an exchange made pursuant to the Act of October 6, 1982 (96 Stat. 1225), the Act of January 12, 1983 (43 U.S.C. 2201 *et seq.*), and section 206 of the Act of October 21, 1976, the land described under items 1 and 2 was reconveyed to the United States.

1. The following described reconveyed land will be opened to the public land laws, but not to the mining and mineral leasing laws:

#### New Mexico Principal Meridian

T. 6 N., R. 3 W.,  
sec. 1, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 3, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , S $\frac{1}{2}$ ;  
sec. 5, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 7, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
sec. 9, W $\frac{1}{2}$ ;  
sec. 19, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ .  
T. 7 N., R. 3 W.,  
sec. 35, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ .

#### T. 6 N., R. 4 W.,

sec. 1, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 3, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 5, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 7, lots 1 to 4, inclusive, S $\frac{1}{2}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ NW $\frac{1}{4}$ , E $\frac{1}{2}$ SW $\frac{1}{4}$ , and SE $\frac{1}{4}$ ;  
secs. 9, 11, 13, 15, and 17;  
sec. 19, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 21, 23, 25, 27 and 29;  
sec. 31, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 33 and 35.

#### T. 6 N., R. 5 W.,

sec. 1, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 3, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 5, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 7, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 9, 13, and 17;  
sec. 19, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 23, 25, and 29;  
sec. 31, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ .

#### T. 7 N., R. 5 W.,

sec. 1, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 3, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 5, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 7, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 9, 11, 13, 15, and 17;  
sec. 19, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 21, 23, 25, 27, and 29;  
sec. 31, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 33 and 35.

The area described contains 34,661.48 acres.

2. The following described reconveyed land is withdrawn by Public Law 100-225 dated December 31, 1987, which established El Malpais National Monument and National Conservation Area (NCA), shall be incorporated into El Malpais National Monument and NCA, and managed in accordance with all laws, rules, and regulations applicable under Public Law 100-225.

#### New Mexico Principal Meridian

##### T. 7 N., R. 11 W.,

sec. 1, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 3, lots 3 and 4, S $\frac{1}{2}$ NW $\frac{1}{4}$ , and SW $\frac{1}{4}$ ;  
sec. 5, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 7, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 9, 11, 13, 15, and 17;  
sec. 19, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 21, 23, 25, 27, and 29;



sec. 31, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 33 and 35.  
T. 8 N., R. 11 W.,  
secs. 11, 13, and 15;  
sec. 19, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
sec. 21, NE $\frac{1}{4}$  and S $\frac{1}{2}$ ;  
secs. 23, 25, 27, and 29;  
sec. 31, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 33 and 35.  
T. 6 N., R. 12 W.,  
sec. 1, lots 1 and 2, S $\frac{1}{2}$ NE $\frac{1}{4}$ , and SE $\frac{1}{4}$ ;  
sec. 3, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 5, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 7, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 9 and 11;  
sec. 13, W $\frac{1}{2}$ ;  
secs. 15 and 17;  
sec. 19, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 21, 23, 25, 27, and 29;  
sec. 31, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
sec. 33;  
T. 7 N., R. 12 W.,  
sec. 1, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 3, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 5, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 7, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 9, 11, 15, and 17;  
sec. 19, lots 2, 3, and 4, E $\frac{1}{2}$ , E $\frac{1}{2}$ NW $\frac{1}{4}$ , and E $\frac{1}{2}$ SW $\frac{1}{4}$ ;  
sec. 21, N $\frac{1}{2}$ ;  
sec. 23, N $\frac{1}{2}$ ;  
secs. 25 and 27;  
sec. 31, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 33 and 35.  
T. 8 N., R. 12 W.,  
sec. 1, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
sec. 3, lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , and S $\frac{1}{2}$ ;  
secs. 11 and 13;  
sec. 15, N $\frac{1}{2}$ ;  
secs. 23 and 25;  
sec. 27, S $\frac{1}{2}$ ;  
sec. 29, S $\frac{1}{2}$ ;  
sec. 31, lots 1 to 4, inclusive, E $\frac{1}{2}$ , and E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
secs. 33 and 35.  
The area described contains 45,082.67 acres.

At 9 a.m. on December 9, 1991, only the land listed under No. 1 will be open to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid applications received at or prior to 9 a.m. on December 9, 1991, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

Dated: October 22, 1991  
Larry L. Woodard,  
State Director.  
[FR Doc. 91-26898 Filed 11-6-91; 8:45 am]  
BILLING CODE 4310-FB-M

[AZ-020-02-4212-13; AZA-25355]

# **Realty Action Exchange of Public Land in Pima, Pinal, and Santa Cruz Counties, AZ**

**AGENCY:** Bureau of Land Management, Interior.  
**ACTION:** Notice of realty action, exchange.

**SUMMARY:** The Bureau of Land Management proposes to exchange public land in order to achieve more efficient management of the public land through consolidation of ownership and the acquisition of unique natural resource lands. All of the following described federal lands have been determined suitable for disposal via exchange pursuant to section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1718:

## **Gila and Salt River Base and Meridian, Pima and Pinal Counties, Arizona**

T. 11 S., R. 8 E.,  
Sec. 28, S $\frac{1}{2}$ N $\frac{1}{2}$ N $\frac{1}{2}$ S $\frac{1}{2}$ N $\frac{1}{2}$ N $\frac{1}{2}$ , S $\frac{1}{2}$ N $\frac{1}{2}$ S $\frac{1}{2}$ N $\frac{1}{2}$ N $\frac{1}{2}$ , S $\frac{1}{2}$ S $\frac{1}{2}$ N $\frac{1}{2}$ N $\frac{1}{2}$ N $\frac{1}{2}$ , S $\frac{1}{2}$ N $\frac{1}{2}$ , S $\frac{1}{2}$ ;  
Sec. 29, all;  
Sec. 32, lots 1, 2, 4, 5, 8, SE $\frac{1}{4}$ SW $\frac{1}{4}$ , SW $\frac{1}{4}$ , SE $\frac{1}{4}$ ;  
Sec. 33, lots 1-4 incl., NE $\frac{1}{4}$  less patented M.S., SE $\frac{1}{4}$  less patented M.S.;  
Sec. 34, lot 1, N $\frac{1}{2}$ , N $\frac{1}{2}$ SW $\frac{1}{4}$ , SE $\frac{1}{4}$ SW $\frac{1}{4}$ , SE $\frac{1}{4}$ .  
T. 12 S., R. 8 E.,  
Sec. 3, lots 9 and 18;  
Sec. 4, five fractions of unpatented mining claims in the S $\frac{1}{2}$ S $\frac{1}{2}$ ;  
Sec. 5, lots 3, 4, 5, 6, 7, lots 2, 18, 12, and 13 less patented mining claims within these lots, S $\frac{1}{2}$ NW $\frac{1}{4}$ , SW $\frac{1}{4}$ , W $\frac{1}{2}$ SE $\frac{1}{4}$ , NE $\frac{1}{4}$  SE $\frac{1}{4}$  less patented mining claims;  
Sec. 10, lot 2;  
Sec. 14, unpatented Eloise mineral survey;  
Sec. 15, unpatented Eloise mineral survey.  
T. 12 S., R. 9 E.,  
Sec. 17, all;  
Sec. 20, N $\frac{1}{2}$ NE $\frac{1}{4}$ , NE $\frac{1}{4}$ NW $\frac{1}{4}$ .  
T. 16 S., R. 12 E.,  
Sec. 35, S $\frac{1}{2}$ SW $\frac{1}{4}$  less patented mining claim, NW $\frac{1}{4}$ SE $\frac{1}{4}$  less patented mining claim.  
T. 17 S., R. 12 E.,  
Sec. 2, M.S. 1649 & 3726, M.S. 2237 & 2294, M.S. 2295, M.S. 3734, M.S. 4295;  
Sec. 11, M.S. 4295, part of N $\frac{1}{2}$ .  
T. 3 S., R. 13 E.,  
Sec. 24, lot 10, SE $\frac{1}{4}$ NE $\frac{1}{4}$ , NE $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
T. 3 S., R. 14 E.,  
Sec. 19, lots 2, 3, 4, E $\frac{1}{2}$ SW $\frac{1}{4}$ ;  
Sec. 29, W $\frac{1}{2}$ , S $\frac{1}{2}$ SE $\frac{1}{4}$ ;  
Sec. 30, N $\frac{1}{2}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ NE $\frac{1}{4}$ , NE $\frac{1}{4}$ NW $\frac{1}{4}$ .  
T. 14 S., R. 18 E.,  
Sec. 7, N $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ , SW $\frac{1}{4}$ NE $\frac{1}{4}$ , W $\frac{1}{2}$  SE $\frac{1}{4}$ NE $\frac{1}{4}$ , E $\frac{1}{2}$ E $\frac{1}{2}$ SW $\frac{1}{4}$ , E $\frac{1}{2}$ W $\frac{1}{2}$ E $\frac{1}{2}$ ;

SW $\frac{1}{4}$ , SW $\frac{1}{4}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ , W $\frac{1}{2}$ SE $\frac{1}{4}$ , W $\frac{1}{2}$ E $\frac{1}{2}$ SE $\frac{1}{4}$ .  
Comprising approximately 5287 acres.

In exchange for the above-described public lands, the United States will acquire all or part of the following parcels of private land located in southern and southcentral Arizona from ASARCO, Incorporated, and Empirita Limited Partnership or their nominees:

T. 14 S., R. 18 E., G&SRM,  
Sec. 8, SE $\frac{1}{4}$ SE $\frac{1}{4}$ .  
T. 17 S., R. 17 E.,  
Sec. 26, E $\frac{1}{2}$ NW $\frac{1}{4}$ .  
T. 17 S., R. 18 E.,  
Sec. 16, All;  
Sec. 17, the east 1560 feet of said section;  
Sec. 20, NE $\frac{1}{4}$ NW $\frac{1}{4}$ , SW $\frac{1}{4}$ SW $\frac{1}{4}$ ;  
Sec. 26, part of W $\frac{1}{2}$ ;  
Sec. 29, NW $\frac{1}{4}$ NW $\frac{1}{4}$ .  
T. 18 S., R. 18 E.,  
Sec. 6, SE $\frac{1}{4}$ SW $\frac{1}{4}$ ;  
Sec. 11, NE $\frac{1}{4}$ , N $\frac{1}{2}$ SE $\frac{1}{4}$ , E $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$ , E $\frac{1}{2}$  NE $\frac{1}{4}$ SW $\frac{1}{4}$ .  
T. 12 S., R. 9 E.,  
Sec. 32, M.S. 3885.  
T. 19 S., R. 18 E.,  
Sec. 9, SE $\frac{1}{4}$ NE $\frac{1}{4}$ ;  
Sec. 10, SW $\frac{1}{4}$ NW $\frac{1}{4}$ , SW $\frac{1}{4}$ ;  
Sec. 15, W $\frac{1}{2}$ SW $\frac{1}{4}$ ;  
Sec. 21, E $\frac{1}{2}$ E $\frac{1}{2}$ ;  
Sec. 22, NW $\frac{1}{4}$ , N $\frac{1}{2}$ SW $\frac{1}{4}$ ;  
Sec. 23, NW $\frac{1}{4}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$ , S $\frac{1}{2}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$ , NW $\frac{1}{4}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ NE $\frac{1}{4}$ ;  
Sec. 27, S $\frac{1}{2}$ N $\frac{1}{2}$ NW $\frac{1}{4}$ , S $\frac{1}{2}$ NW $\frac{1}{4}$ , SW $\frac{1}{4}$ ;  
Sec. 28, E $\frac{1}{2}$ .  
T. 18 S., R. 16 E.,  
Sec. 24, lots 1 to 4, incl., W $\frac{1}{2}$ E $\frac{1}{2}$ , NW $\frac{1}{4}$ .  
T. 20 S., R. 17 E.,  
Sec. 13, E $\frac{1}{2}$ SW $\frac{1}{4}$ , SE $\frac{1}{4}$ ;  
Sec. 24, NE $\frac{1}{4}$ NE $\frac{1}{4}$ , W $\frac{1}{2}$ NE $\frac{1}{4}$ , E $\frac{1}{2}$ NE $\frac{1}{4}$  NW $\frac{1}{4}$ .  
T. 20 S., R. 18 E.,  
Sec. 9, W $\frac{1}{2}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ ;  
Sec. 10, S $\frac{1}{2}$ SW $\frac{1}{4}$ .

The subject parcels to be acquired from Asarco and Empirita Limited Partnership contain critical habitat for the following threatened or endangered or candidate species of plants and animals:

Lesser long-nosed bat (*Leptonycteris curasoae verbaueanae*)  
Nichol's turks head cactus (*Echinocactus horizionthionius* var. *nicholii*)

Gila topminnow (*Poeciliopsis occidentalis occidentalis*)  
Mexican garter snake (*Thamnophis eques*)

Lowland leopard frogs (*Rana yavapiensis*)

Needle-spined pineapple cactus (*Echinomastus erectocentrus* var. *erectocentrus*)<sup>\*</sup>

<sup>\*</sup> = Potential Habitat (unconfirmed)

The exchange proposal involves all of the exchange proponent's interest in the surface and subsurface of the private lands and the surface and subsurface



estate of the public lands. The exchange is consistent with the Bureau's land use planning objectives.

Lands being conveyed from the United States will be subject to certain reservations, terms and conditions including, but not limited to right-of-ways, grazing leases, and permits and all valid existing rights.

The lands to be acquired by the United States from Asarco and Empirita Limited Partnership shall be subject to certain easements, leases, permits and other encumbrances detailed in the subject title reports.

Upon completion of the official appraisal, acreage adjustments will be made to equalize the values of the offered and selected lands.

The lands identified in section 7, Township 14 South, Range 16 East, were reconveyed to the United States by the City of Tucson on October 4, 1989. The land has been determined suitable for private exchange under section 206 of the Federal Land Policy and Management Act.

In accordance with the regulations of 43 CFR 2201.1, publication of this Notice will segregate the affected public land from appropriation under the public land laws, including the mining laws, subject to valid existing rights, except exchange to section 206 of the Federal Land Policy and Management Act of 1976.

The segregation of the above-described land shall terminate upon issuance of a document conveying title to such lands or upon publication in the **Federal Register** of a notice of termination of the segregation; or the expiration of two years from the date of the initial publication of this Notice (August 1, 1991), whichever occurs first.

For a period of forty-five (45) days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027. Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

Dated: October 31, 1991.

Henri R. Bisson,  
District Manager.

[FR Doc. 91-26850 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-32-M

[CO-930-4214-10; COC-1269]

### Proposed Modification of Withdrawal and Opportunity for Public Meeting; Colorado

October 31, 1991.

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The Bureau of Land Management proposes to modify the oil shale withdrawals on 560 acres of public lands to allow for disposal of the surface. This modification will have no effect on the restrictions imposed by the existing withdrawals other than to allow for disposal of the surface by land exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716. The lands continue to be open to oil and gas leasing subject to the restrictions imposed by these withdrawals.

**FOR FURTHER INFORMATION CONTACT:** Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215-7076, 303-239-3706.

**SUPPLEMENTARY INFORMATION:** On October 29, 1991, a petition was approved allowing the Bureau of Land Management to file an application to modify existing withdrawals to allow for disposal of the surface estate of the following described lands:

Sixth Principal Meridian

T. 4 S., R. 94 W.,  
Sec. 26, SW  $\frac{1}{4}$  NW  $\frac{1}{4}$ , S  $\frac{1}{2}$  SW  $\frac{1}{4}$ , and  
SW  $\frac{1}{4}$  SE  $\frac{1}{4}$ ,  
Sec. 34, E  $\frac{1}{2}$  NE  $\frac{1}{4}$  and NE  $\frac{1}{4}$  SE  $\frac{1}{4}$ ,  
Sec. 35, NE  $\frac{1}{4}$  NW  $\frac{1}{4}$ , W  $\frac{1}{2}$  W  $\frac{1}{2}$ , and  
NE  $\frac{1}{4}$  SE  $\frac{1}{4}$ ,  
Sec. 36, NW  $\frac{1}{4}$  SW  $\frac{1}{4}$ .

The areas described aggregate 560 acres in Garfield County.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed modification may present their views in writing to the Colorado State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed modification. All interested persons who desire a public meeting for the purposes of being heard on the proposed action must submit a written request to the Colorado State Director within 90 days of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of time and place will be published in the **Federal Register**

at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR Part 2300.

Robert S. Schmidt,

Chief, Branch of Realty Programs.

[FR Doc. 91-26866 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-JB-M

[NM-030-02-4210-13]

### Exchange of Public Land; Socorro, Catron, and Sierra Counties, NM; Correction

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of correction.

**SUMMARY:** The following corrections are made to the **Federal Register**, Vol. 56, No. 180 (published Tuesday, September 17, 1991), pages 47100 through 47103.

1. On page 47101, third column, under Group 32, change "Proponent: Charles Headen" to "Proponents: Charles and Jessie Headen, Herbert and Alice Cushing."

2. On page 47102, first column, line 8, change "15,406.86 acres" to "20,318.16 acres."

3. On page 47102, third column, under Group 3, line 4, change "NM NM 82775" to "NM NM 82575."

**ADDRESSES:** Bureau of Land Management, Socorro Resource Area, 198 Neel Ave. NW, Socorro, New Mexico 87801.

**FOR FURTHER INFORMATION CONTACT:** Jon Hertz, Socorro Resource Area Office at (505) 835-0412.

Dated: October 28, 1991.

Richard T. Watts,  
Acting District Manager.

[FR Doc. 91-26899 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-FB-M

[NM-940-4214-10; NMNM 86724]

### Proposed Withdrawal and Opportunity for Public Meeting; New Mexico

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The Bureau of Land Management proposed to withdraw 40 acres of public land in Sandoval County, to protect the paleontological resources of the Juana Lopez Research Natural Area (RNA). The notice closes the land for up to 2 years from surface entry and mining. The land will remain open to mineral leasing.



**DATES:** Comments and requests for a public meeting must be received by February 5, 1992.

**ADDRESSES:** Comments and meeting requests should be sent to the New Mexico State Director, BLM, P.O. Box 1449, Santa Fe, New Mexico 87504-1449.

**FOR FURTHER INFORMATION CONTACT:** Clarence F. Hougland, BLM, New Mexico State Office, 505-988-6071.

**SUPPLEMENTARY INFORMATION:** On October 22, 1991, a petition was approved allowing the Bureau of Land Management to file an application to withdraw the following described public land from settlement, sale, location, or entry under the general land laws, including the mining laws, subject to valid existing rights:

New Mexico Principal Meridian

T. 19 N., R. 1 W.,

sec. 14, E $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$  and W $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$ .  
The area described contains 40 acres in Sandoval County.

The purpose of the proposed withdrawal is to protect the paleontological resources of the Juana Lopez RNA.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the New Mexico State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the New Mexico State Director within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the land will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary uses which may be permitted during this segregative period are licenses, permits, cooperative agreements, or discretionary land use authorizations of a temporary nature, but only with the approval of an

authorized officer of the Bureau of Land Management during the segregative period.

Dated: October 31, 1991.

Monte G. Jordan,  
Associate State Director.

[FR Doc. 91-26900 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-FB-M

[NM-940-4214-10; NMNM 86979]

### Proposed Withdrawal and Opportunity for Public Meeting; New Mexico

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The Bureau of Land Management proposes to withdraw 7,320 acres of public land in Sandoval County, to protect the paleontological, geological, recreational, cultural, watershed, and scenic values of the Ojito Area of Critical Environmental Concern (ACEC). This notice closes the land for up to 2 years from surface entry and mining. The land will remain open to mineral leasing.

**DATES:** Comments and requests for a public meeting must be received by February 5, 1992.

**ADDRESSES:** Comments and meeting requests should be sent to the New Mexico State Director, BLM, P.O. Box 1449, Santa Fe, New Mexico 87504-1449.

**FOR FURTHER INFORMATION CONTACT:** Clarence F. Hougland, BLM, New Mexico State Office, 505-988-6071.

**SUPPLEMENTARY INFORMATION:** On October 15, 1991, a petition was approved allowing the Bureau of Land Management to file an application to withdraw the following described public land from settlement, sale, location, or entry under the general land laws, including the mining laws, subject to valid existing rights:

New Mexico Principal Meridian

T. 15 N., R. 1 E.,

sec. 17, E $\frac{1}{2}$ E $\frac{1}{2}$ , NW $\frac{1}{4}$ NE $\frac{1}{4}$ , and W $\frac{1}{2}$ ;

sec. 18, E $\frac{1}{2}$  and SW $\frac{1}{4}$ ;

sec. 19;

sec. 20, E $\frac{1}{2}$ NE $\frac{1}{4}$ , W $\frac{1}{2}$ , and SE $\frac{1}{4}$ ;

sec. 21;

sec. 28, N $\frac{1}{2}$ ;

secs. 29, 30, and 31;

sec. 32, SW $\frac{1}{4}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ SW $\frac{1}{4}$ , and W $\frac{1}{2}$ SE $\frac{1}{4}$ .

T. 15 N., R. 1 W.,

secs. 13, 24, and 25;

sec. 36, SW $\frac{1}{4}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ NW $\frac{1}{4}$ ,

NE $\frac{1}{4}$ SW $\frac{1}{4}$ , and NW $\frac{1}{4}$ SE $\frac{1}{4}$ .

The areas described aggregate 7,320 acres in Sandoval County, New Mexico.

The purpose of the proposed withdrawal is to protect the

paleontological, geological, recreational, cultural, watershed, and scenic values of the Ojito ACEC.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections, in connection with the proposed withdrawal, may present their views in writing to the New Mexico State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the New Mexico State Director within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the land will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary uses which may be permitted during this segregative period are licenses, permits, cooperative agreements, and discretionary land use authorizations of a temporary nature, but only with the approval of an authorized officer of the Bureau of Land Management.

Dated: October 22, 1991.

Larry L. Woodard,  
State Director.

[FR Doc. 91-26901 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-FB-M

### INTERSTATE COMMERCE COMMISSION

[No. 40396 <sup>1</sup>]

### DOJ Petition—Rocky Mountain Carriers

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Notice of filing of petition.

**SUMMARY:** On December 19, 1989, the U.S. Department of Justice (DOJ) filed a

<sup>1</sup> Formerly docketed as Section 5a Application No. 60.



petition with the Commission seeking revocation of the antitrust immunity of Rocky Mountain Motor Tariff Bureau (RMB) to discuss and agree on general rate increases (GRIs). On February 20, 1990, the Commission voted to hold consideration of the petition in abeyance pending completion of the investigation and report in Ex Parte No. MC-196. Investigation of Motor Carrier Collective Ratemaking and Related Practices and Procedures. The report in Ex Parte No. MC-196 was served on May 31, 1991. Investigation of Motor Car. Collective Practices, 7 I.C.C.2d 388 (1991) (Investigation) Our report in Investigation examined and analyzed the issue of coincident pricing by rate bureau members the forms the basis for DOJ's petition. We concluded that the practice had not been shown to be unlawful, because no party presented evidence demonstrating that carriers have engaged in improper discussions before or after any rate bureau meetings, or otherwise colluded unlawfully. 7 I.C.C.2d at 459. We also found, as a general matter, that the practice has not been shown to be contrary to the national transportation policy, because it has not been shown improperly to inflate rate levels, 7 I.C.C.2d at 463. The DOJ petition, as filed, alleges parallel action, but does not establish unlawful collusion. It also alleges, but does not demonstrate, inflated rate levels. Consequently, we decided in Investigation to permit DOJ to file evidence and arguments to address the issues raised by its petition in light of the findings in our report. Accordingly, we invite DOJ to file evidence addressing these issues. If DOJ does not file comments, the proceeding will be discontinued due to a lack of a sufficient record. Upon submission by DOJ of additional arguments and evidence, other interested persons will be permitted to file.

**DATES:** DOJ's evidence is due by January 6, 1992. Replies are due by February 5, 1992.

**ADDRESSES:** Send comments (an original and 15 copies) referring to Docket No. 40396 to: Interstate Commerce Commission, Office of the Secretary, Case Control Branch, Washington, DC 20423.

**FOR FURTHER INFORMATION CONTACT:** Richard B. Felder (202) 275-7691. (TDD for hearing impaired: (202) 275-1721).

**SUPPLEMENTARY INFORMATION:** Additional information is contained in the Commission's decision. To obtain a copy of the full decision, write to, call, or pick up in person from: Office of the Secretary, room 2215, Interstate

Commerce Commission, Washington, DC 20423, telephone (202) 275-7428. Assistance for the hearing impaired is available through TDD service (202) 275-1721.Q02

*It is Ordered:*

1. DOJ's evidence and argument must be filed by January 6, 1992.
2. If DOJ does not timely file comments, the proceeding will be discontinued, without any further Commission action.
3. Upon submission by DOJ of evidence, reply comments are due by February 5, 1992.

Decided: September 25, 1991.

By the Commission, Chairman Philbin, Vice Chairman Emmett, Commissioners Simmons, Phillips, and McDonald.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 91-26861 Filed 11-6-91; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-254 (Sub-No. 3)]

**Providence and Worcester Railroad—Abandonment—Pontiac Secondary Line in Providence and Kent Counties, RI; Findings**

The Commission has found that the public convenience and necessity permit the Providence and Worcester Railroad Company (P&W) to abandon 3.91 miles of railroad extending from Branch Milepost 1.21 to the end of the track at Branch Milepost 5.12, known as the Pontiac secondary line, in Providence and Kent Counties, RI.

A certificate will be issued authorizing abandonment unless by November 22, 1991, the Commission also finds that: (1) A financially responsible person has offered financial assistance (through subsidy or purchase), to enable the rail service to be continued; and (2) it is likely that the assistance would fully compensate the railroad.

Any financial assistance offer must be filed with the Commission and the applicant no later than November 18, 1991. The following notation shall be typed in bold face on the lower left-hand corner of the envelope containing the offer: "Rail Section, AB-OFA". Any offer previously made must be remade within this 10-day period.

Information and procedures regarding financial assistance for continued rail service are contained in 49 assistance for continued rail service are contained in 49 U.S.C. 10905 and 49 CFR 1152.27.

Decided: October 31, 1991.

By the Commission, Chairman Philbin, Vice Chairman Emmett, Commissioners Simmons, Phillips, and McDonald.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 91-26862 Filed 11-6-91; 8:45 am]

BILLING CODE 7035-01-M

**DEPARTMENT OF JUSTICE**

**Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980**

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on October 28, 1991, a proposed Partial Consent Decree in *United States v. Velsicol Chemical Corp. and the City of Memphis*, Civil Action No. 91-2815-FB was lodged with the United States District Court for the Western District of Tennessee. This is an action brought pursuant to section 106 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 as amended by the Superfund Amendments and Reauthorization Act of 1986 ("CERCLA"), 42 U.S.C. 9606. Pursuant to the proposed decree, the settling defendants will finance and perform the Remedial Design and Remedial Action ("RD/RA") at the North Hollywood Dump Superfund Site ("Site"), and reimburse the United States for future oversight costs, operation and maintenance costs, and future response activities.

The Site was a municipal and industrial landfill from the mid-1930's to the mid-1960's. It encompasses approximately 70 acres of land that runs along Hollywood Street in Memphis, Tennessee. Two potentially responsible parties, Velsicol Chemical Corporation and the City of Memphis, have agreed to assume the responsibility for the RD/RA.

The remedy selected for this Site addresses contamination in soils, shallow groundwater, and surface water impoundments at the Site. Pursuant to the proposed Decree, Velsicol and the City will cover the wastes with a low permeability cover on-site. The cover is designed to prevent any further migration of hazardous substances to the groundwater. Implementation and treatment are expected to take five (5) to ten (10) years. The settlement covers 100% of costs associated with the implementation of the RD/RA, including operation and maintenance of the Site and EPA's oversight costs.



The Department of Justice will receive for a period of thirty (30) days from the date of this publication, comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, P.O. Box 7611, Washington, DC 20530. Comments should refer to *United States v. Velsicol Chemical Corp. and the City of Memphis*, D.O.J. Ref. 90-11-2-629.

The proposed Consent Decree may be examined at the Office of the United States Attorney, Western District of Tennessee, 1026 Federal Office Bldg., 167 N. Main Street, Memphis, Tennessee 38103, and at the Environmental Enforcement Section Document Center, 601 Pennsylvania Ave. Building, NW., Washington, DC 20004, (202-347-2072). A copy of the proposed Consent Decree may be obtained in person or by mail from the Environmental Enforcement Section Document Center, P.O. Box 1097, Washington, DC 20004. In requesting a copy by mail, please enclose a check in the amount of \$73.50 (25 cents per page reproduction cost) payable to the "Treasurer of the United States".

Barry M. Hartman,

Acting Assistant Attorney General,  
Environment and Natural Resources Division.  
[FR Doc. 91-26902 Filed 11-6-91; 8:45 am]

BILLING CODE 4410-01-M

## DEPARTMENT OF LABOR

### Senior Executive Service Performance Review Board Membership

**AGENCY:** President's Council on Integrity and Efficiency (PCIE).

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given of the current membership of the PCIE Performance Review Board.

**EFFECTIVE DATE:** October 31, 1991.

**FOR FURTHER INFORMATION CONTACT:** Individual Offices of Inspector General.

**SUPPLEMENTARY INFORMATION:** Section 4314(c)(1) through (5) of title 5, U.S.C. requires each agency to establish in accordance with regulations prescribed by the Office of Personnel Management, one or more SES performance review boards. This board shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive.

Members of the President's Council on Integrity and Efficiency Performance Review Board are:

Members	Title
<b>Agency for International Development</b>	
Corbett M. Flannery.....	Assistant Inspector General for Security.
Gene Richardson.....	Assistant Inspector General for Investigations.
<b>Department of Agriculture</b>	
Charles R. Gillum.....	Deputy Inspector General.
James R. Ebbitt.....	Assistant Inspector General for Audit.
Craig L. Beauchamp.....	Assistant Inspector General for Investigations.
Paula F. Hayes.....	Assistant Inspector General for Policy Development and Resources Management.
Richard Long.....	Deputy Assistant Inspector General for Audit.
Everett Mosley.....	Deputy Assistant Inspector General for Audit.
Jeffrey Rush.....	Deputy Assistant Inspector General for Investigations.
<b>Department of Commerce</b>	
Michael Zimmerman.....	Deputy Inspector General.
J. Steven Sadler.....	Deputy Assistant Inspector General for Regional Audits.
Charles M. Hall.....	Assistant Inspector General for Inspections and Resource Management.
<b>Department of Defense</b>	
Derek J. Vander Schaaf.....	Deputy Inspector General.
Nicholas T. Lutsch.....	Assistant Inspector General for Administration and Information Management.
Jack L. Montgomery.....	Deputy Assistant Inspector General for Administration and Information Management, OAIG, AIM.
David A. Brinkman.....	Assistant Inspector General for Analysis and Follow-up.
Robert J. Lieberman.....	Assistant Inspector General for Auditing.
Edward R. Jones.....	Deputy Assistant Inspector General for Auditing, OAIG, AUD.
Nancy L. Butler.....	Director, Financial Management, Directorate, OAIG, AUDIT.
Donald E. Reed.....	Director, Acquisition Management Directorate, OAIG, AUD.
David K. Steensma.....	Director, Contract Management Directorate, OAIG, AUD.
William F. Thomas.....	Director, Readiness and Operational Support Directorate, OAIG, AUD.
Michael R. Hill.....	Assistant Inspector General for Audit Policy and Oversight.
Donald E. Davis.....	Deputy Assistant Inspector General for Audit Policy and Oversight, OAIG, APO.
Michael B. Suessmann.....	Assistant Inspector General for Departmental Inquiries.
Katherine A. Brittin.....	Assistant Inspector General for Inspections.
Stephen A. Whitlock.....	Director, Inspections Directorate, OAIG, INS.
Donald Mancuso.....	Assistant Inspector General for Investigations.
William G. Dupree.....	Deputy Assistant Inspector General for Investigations, OAIG, INV.

Members	Title
<b>Department of Energy</b>	
Gordon W. Harvey.....	Assistant Inspector General for Audits.
Michael W. Conley.....	Assistant Inspector General for Inspections.
Paul M. Misso.....	Assistant Inspector General for Investigations.
M. Thomas Abruzzo.....	Deputy Assistant Inspector General for Investigations.
Gregory H. Friedman.....	Deputy Assistant Inspector General for Audit for Operations.
Stanley R. Sulak.....	Deputy Assistant Inspector General for Audit Policy, Plans and Programs.
<b>Department of Health and Human Services</b>	
Joseph E. Vengrin.....	Assistant Inspector General for Audit Policy and Oversight.
Robert A. Simon.....	Assistant Inspector General for Criminal Investigations.
<b>Department of Housing and Urban Development</b>	
John J. Connors.....	Deputy Inspector General.
John H. Greer.....	Assistant Inspector General for Audit.
Patrick J. Neri.....	Assistant Inspector General for Investigations.
<b>Department of the Interior</b>	
Joyce N. Fleischman.....	Deputy Inspector General.
Thomas T. Sheehan.....	Assistant Inspector General for Investigations.
Harold Bloom.....	Assistant Inspector General for Audits.
Marvin E. Pierce.....	Deputy Assistant Inspector General for Audits.
<b>Department of Labor</b>	
Charles C. Masten.....	Deputy Inspector General.
Gerald W. Peterson.....	Assistant Inspector General for Audit.
Sylvia T. Horowitz.....	Counsel to the Inspector General.
Joseph Fisch.....	Deputy Assistant Inspector General for Audit.
Irving A. Bassett.....	Assistant Inspector General for Investigations.
Gustave Schick.....	Assistant Inspector General for Labor Racketeering.
E.J. German.....	Assistant Inspector General for Resource Management and Legislative Assessment.
<b>Department of State</b>	
John C. Payne.....	Assistant Inspector General for Audit.
Milton M. MacDonald.....	Deputy Assistant Inspector General for Audit.
Kathleen J. Charles.....	Assistant Inspector General for Policy, Planning and Management.
Beverly C. Lovelady.....	Deputy Assistant Inspector General for Security Oversight.
John Duncan.....	Counsel to the Inspector General.
Robert S. Terjesen.....	Assistant Inspector General for Investigations.
James K. Blubaugh.....	Deputy Assistant Inspector General for Inspections.
<b>Department of Transportation</b>	
Raymond J. DeCarli.....	Assistant Inspector General for Auditing.
Sebastian R. Lorigo.....	Deputy Assistant Inspector General for Investigations.



Members	Title
John W. Lainhart IV.....	Assistant Inspector General for Policy, Planning and Resources.
Lawrence H. Weintraub.....	Deputy Assistant Inspector General for Auditing.

**Department of the Treasury**

Robert P. Cesca.....	Deputy Inspector General.
Jay Weinstein.....	Assistant Inspector General for Audit.
Gary L. Whittington.....	Assistant Inspector General for Policy, Planning and Resources.
Charles D. Fowler III.....	Assistant Inspector General for Investigations.
John N. Balakos.....	Assistant Inspector General for Oversight and Quality Assurance.
Dennis S. Schindel.....	Deputy Assistant Inspector General for Audit Operations.
Karla Cocran.....	Deputy Assistant Inspector General for Audit Program.

**Department of Veterans Affairs**

William T. Merriman.....	Deputy Inspector General.
Michael J. Costello.....	Assistant Inspector General for Investigations.
Alastair M. Connell.....	Assistant Inspector General for Health Care Inspections.
Michael G. Sullivan.....	Assistant Inspector General for Auditing.
John M. Clarkson.....	Deputy Assistant Inspector General for Investigations.
Michael Slachta, Jr. ....	Deputy Assistant Inspector General for Auditing.
Jack H. Kroll.....	Assistant Inspector General for Policy, Planning and Resources.

**Environmental Protection Agency**

James O. Rauch.....	Deputy Assistant Inspector General for Audit.
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**Federal Emergency Management Agency**

William R. Partridge.....	Deputy Inspector General.
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**General Services Administration**

Edward F. Hefferon.....	Deputy Inspector General.
Joel S. Gallay.....	Counsel to the Inspector General.
James E. Henderson.....	Assistant Inspector General for Investigations.
William E. Whyte, Jr. ....	Assistant Inspector General for Auditing.
Lawrence J. Dempsey.....	Assistant Inspector General for Quality Management.

**National Aeronautics and Space Administration**

William D. Hager.....	Assistant Inspector General for Investigations.
Richard J. Pelletier.....	Assistant Inspector General for Auditing.

**Office of Personnel Management**

Harvey D. Thorp.....	Assistant Inspector General for Audits.
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**Railroad Retirement Board**

William J. Doyle III.....	Inspector General.
Charles R. Sekerak.....	Assistant Inspector General for Investigations.

**Small Business Administration**

Stephen N. Marcia.....	Assistant Inspector General for Investigations.
Daniel B. Peyser.....	Counsel to the Inspector General.
Peter L. McClintock.....	Assistant Inspector General for Auditing.

Members	Title
<b>United States Information Agency</b>	
J. Richard Berman.....	Assistant Inspector General for Audit.

Dated: October 31, 1991.

Julian W. De La Rosa,

*Inspector General, Department of Labor, and Chair, PCIE Internal Operations Committee.*

[FR Doc. 91-26933 Filed 11-6-91; 8:45 am]

BILLING CODE 4510-21-M

**Employment and Training Administration**

[TA-W-26,071]

**Nice Specialty Bearings, Kuipsville, PA; Negative Determination Regarding Application for Reconsideration**

By an application dated September 17, 1991, after being granted a filing extension, the company requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice will soon be published in the **Federal Register**.

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a mis-interpretation of facts or of the law justified reconsideration of the decision.

The company claims that the Department's survey considered only the first half of 1991 compared to the same half in 1990. Its also claimed that none of the domestic bidders could manufacture the quality bearings needed; consequently, its major customer went overseas.

Investigation findings show that the decreased employment criterion of the Group Eligibility Requirements of the Trade Act of 1974 was not met for the period 1989 to 1990. Also, the petition specifically stated it was for worker separations occurring in 1991. The lost bid survey shows that the date of the award is January 1, 1991.

The Department's denial was based on the fact that the "contributed importantly" test of the Group Eligibility Requirements of the Trade Act was not

met. This test is generally demonstrated through a survey of the workers' firm's customers. The Department's lost bid survey for Nice Specialty Bearings' major customer showed that it was not the lowest domestic bidder for the ball bearing project in the period relevant to the petition.

Other findings show that Nice Specialty Bearings identified capacity and certain other problems in supplying ball bearings to its major customer. As a temporary measure the major customer went to another domestic firm for ball bearings. However, this subsequent firm did not qualify as a long term viable source. Nice's major customer then conducted a market test to resource its ball bearing business and Nice Specialty Bearings was not the lowest domestic bidder.

**Conclusion**

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 29th day of October 1991.

Stephen A. Wandner,

*Deputy Director, Office of Legislation & Actuarial Services, Unemployment Insurance Service.*

[FR Doc. 91-26934 Filed 11-6-91; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-26,370]

**Proctor and Gamble Manufacturing Co., Avenel, NJ; Termination of Investigation**

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on September 23, 1991 in response to a worker petition which was filed on September 23, 1991 on behalf of workers at The Proctor and Gamble Manufacturing Company, Avenel, New Jersey.

A negative determination applicable to the petitioning group of workers was issued on July 23, 1991 (TA-W-25,882). No new information is evident which would result in a reversal of the Department's previous determination. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.



Signed at Washington, DC this 29th day of October 1991.

**Marvin M. Fooks,**

*Director, Office of Trade Adjustment Assistance.*

[FR Doc. 91-26935 Filed 11-6-91; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-26,371]

**The Proctor and Gamble Manufacturing Co.; Staten Island, NY; Termination of Investigation**

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on September 23, 1991 in response to a worker petition which was filed on September 23, 1991 on behalf of workers at The Proctor and Gamble Manufacturing Company, Staten Island, New York.

An active certification covering the petitioning group of workers remains in effect (TA-W-25,883). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 29th day of October 1991.

**Marvin M. Fooks,**

*Director, Office of Trade Adjustment Assistance.*

[FR Doc. 91-26936 Filed 11-6-91; 8:45 am]

BILLING CODE 4510-30-M.

**Job Training Partnership Act: Native American Programs' Advisory Committee; Appointment of Members**

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice of appointment of members.

**SUMMARY:** Notice is hereby given that appointments have been made to fill twenty-one (21) vacancies on the Job Training Partnership Act Native American Programs' Advisory Committee.

The membership of the Committee and categories represented are as follows:

**Representing JTPA Section 401 Grantees**

Mr. Terry Polchies\*\*, Executive Director, Central Maine Indian Association, Inc., Bangor, Maine.

Ms. Joan H. Cofield\*\*, JTPA Director, Powhatan-Renape Nation, Rancocas, New Jersey.

Mr. John R. Hassan\*, JTPA Director, Council of Three Rivers, American Indian Center, Inc., Pittsburgh, Pennsylvania.

Mr. Eddie L. Tullis\*, Chairman, Poarch Band of Creek Indians, Atmore, Alabama.

Mr. Dean Braggalla\*\*, JTPA Director, Leech Lake Reservation, Cass Lake, Minnesota.

Mr. Robert E. Lewis\*\*, Governor, Pueblo of Zuni, Zuni, New Mexico.

Mr. Frank LaMere\*, Executive Director, Nebraska Indian Inter-Tribal Development Corporation, Winnebago, Nebraska.

Mr. Wilbur Red Tomahawk\*\*, JTPA Director, Standing Rock Sioux Tribe, Fort Yates, North Dakota.

Ms. Joy J. Hanley\*, Executive Director, Affiliation of Arizona Indian Centers, Inc., Phoenix, Arizona.

Ms. Lois E. Lemery\*\*, Program Manager, Colville Confederated Tribes, Nespelem, Washington.

Ms. Donna L. Scott\*\*, Director of Employment & Training, Tanana Chiefs Conference, Inc., Fairbanks, Alaska.

Ms. Winona Whitman\*, Employment & Training Program Administrator, Alu Like, Inc., Honolulu, Hawaii.

**Representing**

**National Organizations**

Mr. Norman C. DeWeaver\*, Washington, D.C. Representative, Indian and Native American Employment, and Training Coalition, Washington, DC.

Ms. LeeAnn Tall Bear\*\*, Executive Director, National American Indian Council, Washington, DC.

**Representatives From Other Disciplines**

Mr. Dale Wing\*, Assistant Project Director, American Association of Retired People, Washington, DC.

Dr. Rose-Alma McDonald-Jacobs\*, Native American Consultant, Hogsburg, New York.

Mr. Clarence W. Skye\*\*, Executive Director, United Sioux Tribes of South Dakota, Pierre, South Dakota.

Mr. Gaiashkibos\*\*, Chairman, Lac Courte Oreilles, Tribal Governing Board, Hayward, Wisconsin.

Mr. Donald Denetdeal\*, Acting Dean, Navajo Community College, Ganado, Arizona.

Mr. Stuart Tonemah\*, President, Center Five Evaluation Center, Norman, Oklahoma.

Mr. Robert Martin\*\*, President, Haskell Indian College, Lawrence, Kansas.

\* These members have been appointed for a term which will end on September 24, 1992.

\*\* These members have been appointed for a term which will end on September 24, 1993.

The JTPA Native American Programs' Advisory Committee was established under section 401(h)(1) of title IV of JTPA to advise the Assistant Secretary for Employment and Training on rules, regulations and performance standards specifically and solely for Native American programs authorized under that section.

**DATES:** These appointments were made and were effective on October 17, 1991. Ten of these appointments will expire on September 24, 1992 and the remaining eleven will expire on September 24, 1993.

**FOR ADDITIONAL INFORMATION CONTACT:** Paul A. Mayrand, Director, Office of Special Targeted Programs, Employment and Training Administration, room N-

4641, 200 Constitution Avenue, NW., Washington, DC 20210; Telephone: (202) 535-0500 (this is not a toll-free number).

Signed at Washington, DC, 31st day of October, 1991.

**Robert T. Jones,**

*Assistant Secretary of Labor.*

[FR Doc. 91-26937 Filed 11-6-91; 8:45 am]

BILLING CODE 4510-30-M

**Federal-State Unemployment Compensation Program: Certifications Under the Federal Unemployment Tax Act for 1991**

On October 31, 1991, the Secretary of Labor signed the annual certifications under the Federal Unemployment Tax Act, 26 U.S.C. 3301 et seq., thereby enabling employers who make contributions to State unemployment funds to obtain certain credits for their liability for the Federal unemployment tax. By letter of the same date the certifications were transmitted to the Secretary of the Treasury. The letter and the certifications are printed below.

Dated: October 31, 1991.

**Roberts T. Jones,**

*Assistant Secretary of Labor.*

October 31, 1991.

The Honorable Nicholas F. Brady,  
*Secretary of the Treasury, Washington, D.C.*  
20220.

Dear Secretary Brady: Transmitted herewith are an original and one copy of the certifications of the States and their unemployment compensation laws for the 12-month period ending on October 31, 1991. One is required with respect to normal Federal unemployment tax credit by section 3304 of the Internal Revenue Code of 1986, and the other is required with respect to additional tax credit by section 3303 of the Code.

The certification pursuant to section 3304 lists all 53 jurisdictions, except New Jersey. As was the case for the last two years, New Jersey is omitted from both certifications because of issues arising under the requirements of section 3304(a) of the Internal Revenue Code of 1986. An agreement has been reached with the State of New Jersey, and, as the State fulfills its obligations under this agreement, I will forward to you the certifications with respect to New Jersey as appropriate. The certification pursuant to section 3303 also omits Puerto Rico because the unemployment compensation law of this jurisdiction permitted no reduced rates of contributions for 1991. We note that Puerto Rico plans on assigning rates based on experience beginning on January 1, 1992.

Sincerely,

Lynn Martin  
Enclosures



### Certification of States to the Secretary of the Treasury Pursuant to Section 3304 of the Internal Revenue Code of 1986

In accordance with the provisions of section 3304(c) of the Internal Revenue Code of 1986 (26 U.S.C. 3304(c)), I hereby certify the following named States to the Secretary of the Treasury for the 12-month period ending on October 31, 1991, in regard to the unemployment compensation laws of those States which heretofore have been approved under the Federal Unemployment Tax Act.

Alabama	Montana
Alaska	Nebraska
Arizona	Nevada
Arkansas	New Hampshire
California	New Mexico
Colorado	New York
Connecticut	North Carolina
Delaware	North Dakota
District of Columbia	Ohio
Florida	Oklahoma
Georgia	Oregon
Hawaii	Pennsylvania
Idaho	Puerto Rico
Illinois	Rhode Island
Indiana	South Carolina
Iowa	South Dakota
Kansas	Tennessee
Kentucky	Texas
Louisiana	Utah
Maine	Vermont
Maryland	Virginia
Massachusetts	Virgin Islands
Michigan	Washington
Minnesota	West Virginia
Mississippi	Wisconsin
Missouri	Wyoming

This certification is for the maximum normal credit allowable under section 3302(a) of the Code.

Signed at Washington, DC, on October 31, 1991.

Lynn Martin,  
Secretary of Labor.

### Certification of State Unemployment Compensation Laws to the Secretary of the Treasury Pursuant to Section 3303(b)(1) of the Internal Revenue Code of 1986

In accordance with the provisions of paragraph (1) of section 3303(b) of the Internal Revenue Code of 1986 (26 U.S.C. 3303(b)(1)), I hereby certify the unemployment compensation laws of the following named States, which heretofore have been certified pursuant to paragraph (3) of section 3303(b) of the Code, to the Secretary of the Treasury for the 12-month period ending on October 31, 1991:

Alabama	Florida
Alaska	Georgia
Arizona	Hawaii
Arkansas	Idaho
California	Illinois
Colorado	Indiana
Connecticut	Iowa
Delaware	Kansas
District of Columbia	Kentucky

Louisiana  
Maine  
Maryland  
Massachusetts  
Michigan  
Minnesota  
Mississippi  
Missouri  
Montana  
Nebraska  
Nevada  
New Hampshire  
New Mexico  
New York  
North Carolina  
North Dakota  
Ohio

Oklahoma  
Oregon  
Pennsylvania  
Rhode Island  
South Carolina  
South Dakota  
Tennessee  
Texas  
Utah  
Vermont  
Virginia  
Virgin Islands  
Washington  
West Virginia  
Wisconsin  
Wyoming

This certification is for the maximum additional credit allowable under section 3302(b) of the Code.

Signed at Washington, DC, on October 31, 1991.

Lynn Martin,  
Secretary of Labor.

[FR Doc. 91-26938 Filed 11-6-91; 8:45 am]

BILLING CODE 4510-30-M

### NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 91-100]

#### NASA Advisory Council (NAC), Space Science and Applications Advisory Committee (SSAAC), Solar System Exploration Subcommittee; Meeting

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Space Science and Applications Advisory Committee, Solar System Exploration Subcommittee.

**DATES:** November 14, 1991, 8:30 a.m. to 5:30 p.m.; and November 15, 1991, 8:30 a.m. to 12:30 p.m.

**ADDRESSES:** California Institute of Technology, room 102, Building 100, 770 S. Wilson, Pasadena, CA 91101.

**FOR FURTHER INFORMATION CONTACT:** Dr. Wesley Huntress, Code SL, National Aeronautics and Space Administration, Washington, DC 20546 (202/453-1588).

**SUPPLEMENTARY INFORMATION:** The Space Science and Applications Advisory Committee consults with and advises the NASA Office of Space Science and Applications (OSSA) on long-range plans for, work in progress on, and accomplishments of NASA's Space Science and Applications programs. The Solar System Exploration Subcommittee (SSES) provides advice to

the Solar System Exploration Division concerning long-range planning in solar system exploration. The SSES will meet to discuss the OSSA program, Fiscal Year 1992 budget, strategic planning, and activities of the SSAAC and working groups. The Subcommittee is chaired by Dr. Jonathan Lunine and is composed of 25 members. The meeting will be closed to the public from 8:30 a.m. to 9 a.m. on November 15, 1991, for a discussion of the qualifications of additional candidates for membership. Such a discussion would invade the privacy of the candidates and other individuals involved. Since this discussion will be concerned with matters listed in 5 U.S.C. 552b(c)(6), it has been determined that the meeting will be closed to the public for this period of time. The remainder of the meeting will be open to the public up to the seating capacity of the room (approximately 50 people including members of the Subcommittee). It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

#### Type of Meeting

Open—except for the closed session noted in the agenda below.

#### Agenda

Thursday, November 14

8:30 a.m.—Opening Remarks.

8:45 a.m.—Status of the OSSA Program and Fiscal year 1992 Budget.

9:45 a.m.—Briefing on International Space Year.

10:15 a.m.—Review of Action Items from the Woods Hole and November SSAAC Meetings.

1 p.m.—Report from Lunar Exploration Science Working Group.

2 p.m.—Report from Mars Science Working Group.

3:15 p.m.—Discovery Presentations and Discussion: Jet Propulsion Laboratory and Applied Physics Laboratory.

4:45 p.m.—Rover Robotics Demonstration.

5:30 p.m.—Adjourn.

Friday, November 15

8:30 a.m.—Closed Session.

9 a.m.—Strategic Planning Discussion.

10 a.m.—Instrument Development: University/NASA/Industry.

11 a.m.—Research and Analysis Study.

Noon—Subcommittee Discussion.

12:30 p.m.—Adjourn.

Dated: October 31, 1991.

John W. Gaff,

Advisory Committee Management Officer,  
National Aeronautics and Space Administration.

[FR Doc. 91-26914 Filed 11-6-91; 8:45 am]

BILLING CODE 7510-01-M



# **NATIONAL COMMISSION ON SEVERELY DISTRESSED PUBLIC HOUSING**

## **Meetings/Public Hearings Announcement**

**AGENCY:** National Commission on Severely Distressed Public Housing.

**ACTION:** Notice of public hearings.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Commission on Severely Distressed Public Housing announces a forthcoming meeting of the Commission.

**DATES:** Wednesday, November 20, 1991, 8:30 a.m. until 11:30 a.m., Thursday, November 21, 1991, 9 a.m. until 5 p.m.

**ADDRESSES:** United States Capitol, Reception Room EF100, Independence Avenue & 1st Street, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Carmelita Pratt, Administrative Officer, The National Commission on Severely Distressed Public Housing, 1100 L Street, NW., #7121, Washington, DC 20005 (202) 275-6933.

**TYPE OF MEETING:** Open.

Carmelita R. Pratt,  
Administrative Officer.

[FR Doc. 91-26918 Filed 11-6-91; 8:45 am]

BILLING CODE 6620-07-M

## **NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES**

### **Meeting of the National Council on the Arts**

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the National Council on the Arts will be held on November 23, 1991, from 9 a.m.-5:30 p.m. in the Alexandria Room, Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202.

This meeting will be open to the public on a space available basis. The topics will include the role of the Council and other policy issues.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW.,

Washington, DC 20506, 202/682-5532, TTY 202/682-5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call (202) 682-5433.

Dated: November 4, 1991.

Yvonne M. Sabine,

Director, Council and Panel Operations,  
National Endowment for the Arts.

[FR Doc. 91-26917 Filed 11-6-91; 8:45 am]

BILLING CODE 7537-01-M

## **NATIONAL SCIENCE FOUNDATION**

### **Special Emphasis Panel in Cross-Disciplinary Activities**

**SUMMARY:** In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is to review and evaluate proposals and provide advice and recommendations as part of the selection process for awards. Because the proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with proposals, the meetings are closed to the public. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

**Name:** Special Emphasis Panel in Cross-Disciplinary Activities.

**Dates & Times:** December 5-6, 1991 8:30 am-5 pm.

**Location:** National Science Foundation 1800 G Street, NW, Washington, DC 20550 room 1243.

**Type of meeting:** Closed.

**Agenda:** Review and evaluate CISE Instrumentation proposals.

**Contact person:** Barbara Palmer, room 436, National Science Foundation, Washington, DC 20550. Telephone (202) 357-7349.

Dated November 4, 1991.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 91-26919 Filed 11-6-91 8:45 am]

BILLING CODE 7555-01-M

### **Meeting of the Special Emphasis Panel in Mathematical Sciences**

The National Science Foundation announces the following meeting:

**Name:** Special Emphasis in Mathematical Sciences.

**Date and time:** December 6, 1991 (8:30 a.m. to 10 p.m.) and December 7, 1991 (8:30 a.m. to noon)

**Place:** American Mathematical Society, 201 Charles Street, Providence, RI 02904.

**Type of meeting:** Closed.

**Contact Person:** Dr. Deborah F. Lockhart, Office of Special Projects, Division of Mathematical Sciences, National Science Foundation, room 339, 1800 G Street, NW., Washington, DC 20550, (202) 357-3453.

**Purpose of Meeting:** To evaluate applications and provide recommendations on those applications as part of the selection process for the NSF Mathematical Sciences Postdoctoral Research Fellowship program.

**Agenda:** Discussion and evaluation of and recommendations for applications for Mathematical Sciences Postdoctoral Research Fellowships.

**Reason for Closing:** The applications being reviewed include information of a confidential nature, including technical information and personal information concerning individuals associated with the applications. These matters are within exemptions 4 and 6 of the Government in the Sunshine Act.

Dated: November 4, 1991.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 91-26920 Filed 11-6-91; 8:45 am]

BILLING CODE 7555-01-M

## **NUCLEAR REGULATORY COMMISSION**

[Docket Nos. 50-498 and 50-499]

**Houston Lighting & Power Co.; City Public Service Board of San Antonio; Central Power and Light Co.; City of Austin, TX; Environmental Assessment and Finding of No Significant Impact**

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from the scheduler requirements of 10 CFR 50.54(t) to Houston Lighting & Power Company, et al. (the licensee), for operation of the South Texas Project, Units 1 and 2, located in Matagorda County, Texas.

### **Environmental Assessment**

#### **Identification of Proposed Action**

The proposed action would grant an exemption from the requirement of 10 CFR 50.54(t) to review its emergency preparedness program at least every 12



months by persons who have no direct responsibility for implementation of the emergency preparedness program. By letter dated July 19, 1991, as supplemental on September 20, 1991, the licensee requested an exemption from 10 CFR 50.54(t) which would defer the completion of the emergency preparedness program audit for three months beyond the current schedule of September 1991.

#### *The Need for the Proposed Action*

Section 50.54(t) of title 10 of the Code of Federal Regulations requires the licensee to review its emergency preparedness program at least every 12 months by person who have no direct responsibility for implementation of the emergency preparedness program. A major enhancement of the South Texas Project, Units 1 and 2, emergency preparedness program was implemented in August 1991, and annual retraining of the emergency response organization was delayed to August 1, 1991, to allow inclusion of the enhanced emergency preparedness program. The exemption to December 1991 will allow for an evaluation of the enhanced emergency preparedness program after four months of implementation.

#### *Environmental Impacts of the Proposed Action*

The proposed exemption affects only the licensee's required date for reviewing its emergency preparedness program. Thus, post-accident radiological releases will not differ from those determined previously, and the proposed exemption does not otherwise affect facility radiological effluents, or any significant occupational exposures. With regard to potential non-radiological impacts, the proposed exemption does not affect plant non-radiological effluents and has no other environmental impact. Therefore, the Commission concludes that there are no measurable radiological or non-radiological environmental impacts associated with the proposed exemption.

#### *Alternative to the Proposed Action*

Since the Commission has concluded there is no measurable environmental impact associated with the proposed exemption, any alternatives either will have no environmental impact or will have a greater environmental impact. The principal alternative to the exemption would be to require an earlier date for the independent review of the emergency preparedness program. Such an action would not enhance the protection of the environment. The exemption to December 1991 will allow

for an evaluation of the enhanced emergency preparedness program after four months of implementation.

#### *Alternative Use of Resources*

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for the South Texas Project, Units 1 and 2, dated August 1986.

#### *Agencies and Persons Consulted*

The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

#### *Finding of No Significant Impact*

The Commission has determined not to prepare an environmental impact statement for the proposed exemption. Based upon the environmental assessment, the NRC staff concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the licensee's letters dated July 19, 1991, and September 20, 1991. The letters are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the Wharton County Junior College, J.M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488.

Dated at Rockville, Maryland, this 31st day of October 1991.

For the Nuclear Regulatory Commission,  
**George F. Dick,**

*Acting Director, Project Directorate IV-2,  
Division of Reactor Projects—III/IV/V,  
Office of Nuclear Reactor Regulation.*  
[FR Doc. 91-26911 Filed 11-6-91; 8:45 am]

BILLING CODE 7590-01-M

## OFFICE OF SCIENCE AND TECHNOLOGY POLICY

### Meeting of the President's Council of Advisors on Science and Technology

The President's Council of Advisors on Science and Technology will meet on November 14-15, 1991. The meeting will begin at 9 a.m. in the Conference Room, Council on Environmental Quality, 722 Jackson Place, NW., Washington, DC. The meeting will conclude at approximately 12 noon on Friday.

The purpose of the Council is to advise the President on matters involving science and technology.

#### *Proposed Agenda*

1. Briefing of the Council on the current activities of the Office of

Science and Technology Policy and of the private sector.

2. Briefing of the Council on current federal activities and policies in science and technology.

3. Discussion of progress of working group panels.

Portions of the November 14-15 sessions will be closed to the public.

The briefing on some of the current activities of OSTP necessarily will involve discussion of materials that are formally classified in the interest of national defense or for foreign policy reasons. This is also true for a portion of the briefing on panel studies. As well, a portion of both of these briefings will require discussion of internal personnel procedures of the Executive Office of the President and information which, if prematurely disclosed, would significantly frustrate the implementation of decisions made requiring agency action. These portions of the meeting will be closed to the public pursuant to 5 U.S.C. 522b(c)(1), (2), and (9)(B).

A portion of the discussion of panel composition will necessitate discussion of information of a personal nature. Accordingly, this portion of the meeting will also be closed to the public, pursuant to 5 U.S.C. 552b(C)(6).

Because of the security requirements, persons wishing to attend the open portion of the meeting should contact Ms. Ann Barnett (202) 395-4692, prior to 3 p.m. on November 13, 1991. Ms. Barnett is available to provide specific information regarding time, place, and agenda.

Dated: October 28, 1991.

**Ms. Damar W. Hawkins,**  
*Executive Assistant, Office of Science and Technology Policy.*

[FR Doc. 91-26809 Filed 11-6-91; 8:45 am]

BILLING CODE 3170-01-M

## OVERSIGHT BOARD

### Region I Advisory Board Meeting; Change of Meeting Time

**AGENCY:** Oversight Board.

**ACTION:** Change of meeting time.

**SUMMARY:** This is to announce a time change for the Region I Advisory Board meeting scheduled for Tuesday, November 13, 1991, at 12:30 pm, Tampa, Fla., as originally published in the *Federal Register*, October 28, 1991, 56 FR 55515. The new time is listed below.

**DATES:** Tuesday, November 13, 1991, 9 a.m. to 12 noon, Region I Advisory Board.



**ADDRESSES:** Tampa Bay Performing Arts Center, Banquet Hall, Second Level, 1010 North W.C. MacInnes Place, Tampa, Florida.

**FOR FURTHER INFORMATION CONTACT:**

Jill Nevius, Committee Management Officer, 1777 F Street, NW., Washington, DC 20232, (202) 786-9672.

Dated: November 5, 1991.

Jill Nevius,

*Committee Management Officer.*

[FR Doc. 91-26995 Filed 11-6-91; 11:05 am]

BILLING CODE 2222-01-M

## POSTAL RATE COMMISSION

[Docket No. A92-1; Order No. 907]

**Sample, Kentucky 40163 (Ed Kidwell, Petitioner); Notice and Order Accepting Appeal and Establishing Procedural Schedule Under 39 U.S.C. 404(b)(5)**

Issued November 4, 1991.

*Docket Number:* A92-1.

*Name of Affected Post Office:* Sample, Kentucky 40163.

*Name(s) of Petitioner(s):* Ed Kidwell.

*Type of Determination:* Closing.

*Date of Filing of Appeal Papers:* October 31, 1991.

*Categories of Issues Apparently Raised:*

1. Effect on postal services [39 U.S.C. 404(b)(2)(C)].
2. Effect on employees [39 U.S.C. 404(b)(2)(B)].
3. Economic savings [39 U.S.C. 404(b)(2)(D)].

Other legal issues may be disclosed by the record when it is filed; or, conversely, the determination made by the Postal Service may be found to dispose of one or more of these issues.

In the interest of expedition, in light of the 120-day decision schedule [39 U.S.C. 404(b)(5)], the Commission reserves the right to request of the Postal Service memoranda of law on any appropriate issue. If requested, such memoranda will be due 20 days from the issuance of the request; a copy shall be served on the petitioner. In a brief or motion to dismiss or affirm, the Postal Service may incorporate by reference any such memoranda previously filed.

*The Commission orders:* (A) The record in this appeal shall be filed on or before November 15, 1991.

(B) The Secretary shall publish this Notice and Order and Procedural Schedule in the **Federal Register**.

By the Commission.

**Charles L. Clapp,**

*Secretary.*

### Appendix

October 31, 1991—Filing of Petition.

November 4, 1991—Notice and Order of Filing of Appeal.

November 25, 1991—Last day for filing of petitions to intervene [see 39 CFR 3001.111(b)].

December 5, 1991—Petitioner's Participant Statement or Initial Brief [see 39 CFR 3001.115 (a) and (b)].

December 30, 1991—Postal Service Answering Brief [see 39 CFR 3001.115(c)].

January 14, 1992—Petitioner's Reply Brief should petitioner choose to file one [see 39 CFR 3001.115(d)].

January 21, 1992—Deadline for motions by any party requesting oral argument. The Commission will schedule oral argument only when it is a necessary addition to the written filing [see 39 CFR 3001.116].

February 28, 1992—Expiration of 120-day decisional schedule [see 39 U.S.C. 404(b)(5)].

[FR Doc. 91-26926 Filed 11-6-91; 8:45 am]

BILLING CODE 7710-FW-M

## RAILROAD RETIREMENT BOARD

### Agency Forms Submitted for OMB Review

**AGENCY:** Railroad Retirement Board.

**ACTION:** In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the Railroad Retirement Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

### Summary of Proposal(s)

(1) *Collection title:* Statements of Claimed Railroad Service and Earnings.

(2) *Form(s) submitted:* UI-9, UI-23, ID-4F, ID-4U, ID-4X, ID-4Y, ID-20-1, ID-20-2, ID-20-4, ID-20-5, ID-20-7.

(3) *OMB Number:* 3220-0025.

(4) *Expiration date of current OMB clearance:* Three years from date of OMB approval.

(5) *Type of request:* Revision of a currently approved collection.

(6) *Frequency of response:* On occasion.

(7) *Respondents:* Individuals or households.

(8) *Estimated annual number of respondents:* 5,725.

(9) *Total annual responses:* 5,725.

(10) *Average time per response:* .10096 hours.

(11) *Total annual reporting hours:* 578.

(12) *Collection description:* When the railroad service and/or compensation

on the RRB's records is insufficient to qualify a claimant for unemployment or sickness benefits, the statements obtain information needed to reconcile the compensation and/or service on record with that claimed by the employee.

### ADDITIONAL INFORMATION OR

**COMMENTS:** Copies of the proposed forms and supporting documents can be obtained from Dennis Eagan, the agency clearance officer (312-751-4693). Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611 and the OMB reviewer, Laura Oliven (202-395-7316), Office of Management and Budget, room 3002, New Executive Office Building, Washington, DC 20503.

**Dennis Eagan,**

*Clearance Officer.*

[FR Doc. 91-26903 Filed 11-6-91; 8:45 am]

BILLING CODE 7905-01-M

## SECURITIES AND EXCHANGE COMMISSION

### Forms Under Review by Office of Management and Budget

Agency Clearance Officer: Kenneth A. Fogash (202) 272-2142

Upon written request copy available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

### Revisions

File No. 270-2, Regulation S-K

File No. 270-287, Form S-4

File No. 270-288, Form F-4

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission has submitted for OMB approval revision of the following: Forms S-4 and F-4, as well as Regulation S-K. The forms and regulation provide a basis for the Commission to fulfill its statutory responsibility to ensure that issuers of publicly traded securities provide investors and the marketplace with adequate information. Form S-4 affects approximately 502 filers for a total of 740,450 burden hours; Form F-4 affects approximately 2 filers for a total of 2,810 burden hours; and Regulations S-K is assigned 1 burden hour for administrative convenience. The estimated burden hours are made solely for purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a



representative survey or study of the costs of the Commission's rules and forms.

Direct general comments to Gary Waxman at the address below. Direct any comments concerning the accuracy of the estimated average burden hours for compliance with SEC rules and forms to Kenneth A. Fogash, Deputy Executive Director, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549 and Gary Waxman, Clearance Officer, Office of Management and Budget (Paperwork Reduction Project 3235-0071, 0324, and 0325), New Executive Office Building, room 3228, Washington, DC 20503.

Dated: October 31, 1991.

Margaret H. McFarland,  
Deputy Secretary.

[FR Doc. 91-26921 Filed 11-6-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-29893; File No. SR-NASD-90-53]

**Self-Regulatory Organizations;  
National Association of Securities  
Dealers, Inc.; Order Granting Partial  
Approval of Proposed Rule Change  
Relating to Sanctions for Violation of  
the NASD Rules**

November 1, 1991.

The National Association of Securities Dealers, Inc. ("NASD" or "Association") submitted to the Securities and Exchange Commission ("SEC" or "Commission") on October 16, 1990 a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> to amend Article V, sections 1 and 3 of the NASD Rules of Fair Practice.<sup>2</sup>

Notice of the proposed rule change, as amended by Amendment No. 1,<sup>3</sup> together with the terms of substance of the proposal was provided by the issuance of a Commission release (Securities Exchange Act Release No. 28657, November 29, 1990) and by publication in the Federal Register (55 FR 50432, December 6, 1990). No comments were received on the proposed rule change. This order

approves, in part, the proposed rule change. Specifically, this order approves the proposed amendments to Article V, sections 1 and 3 of the NASD Rules of Fair Practice.

The proposed amendment to Article V, section 1 of the Rules of Fair Practice would generally change the term "penalty" to "sanction" and authorize the National Business Conduct Committee ("NBCC") to impose sanctions for violations of NASD rules. The proposed amendment to section 3 of the Rules of Fair Practice would authorize the NBCC to impose costs of disciplinary proceedings on respondents.

The NASD is proposing these amendments to conform these rules to changes made to the Code of Procedure in SR-NASD-90-35,<sup>4</sup> which implemented a recommendation of the Special Committee on NASD Structure and Governance. Basically, SR-NASD-90-35 provides that decisions of the NBCC are the final decisions of the NASD in disciplinary cases and do not require action by the full Board of Governors to become effective.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of section 15A and the rules and regulations thereunder. Specifically, the proposed rule change is consistent with the provisions of section 15A(b)(7) of the Act, which requires, among other things, that the rules of the NASD provide that its members and persons associated with its members shall be appropriately disciplined for violations of any provision of this title, the rules or regulations thereunder, or the rules of the Association, by expulsion, suspension, limitations of activities, functions, and operations, fines, censure, being suspended or barred from being associated with a member, or any other fitting sanction.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed amendments to Article V, sections 1 and 3 contained in SR-NASD-90-53, be, and hereby are approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-26922 Filed 11-6-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-29882; File No. SR-PSE-91-29]

**Self-Regulatory Organizations; Pacific  
Stock Exchange, Inc.; Order Granting  
Approval to Proposed Rule Change  
Relating to the Pacific Stock  
Exchange's Amendments to its Listing  
Fees Schedule**

October 29, 1991.

On August 26, 1991, the Pacific Stock Exchange, Inc. ("PSE" or "Exchange") submitted to the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to adopt and increase listing, maintenance and application processing fees.<sup>3</sup>

The proposed rule change was published for comment in Securities Exchange Act Release No. 29679 (September 12, 1991), 56 FR 47507 (September 19, 1991). No comments were received on the proposal.

Currently, the Exchange's listing fees include an original listing fee of \$7,500 for primary issues (i.e., common stock) and \$2,500 each for additional classes of common stock and secondary issues (i.e., preferred stock, warrants, bonds, and rights).<sup>4</sup> To list additional shares of common stock or warrants, the fee is \$.0025 per share; however, the Exchange imposes, per application, a minimum charge of \$500 and a maximum of \$7,500 as well as an annual maximum of \$15,000. To substitute an original listing, there is a fixed fee of \$2,500 per application.<sup>5</sup> Lastly, the PSE currently charges an annual maintenance fee of \$1,000 for the first issue and \$250 for each additional issue, with a maximum charge of \$3,000, which are payable the January of each year following listing.

The Exchange proposes to increase two of these listing fees. The fee for an original listing of common stock would be raised to \$10,000.<sup>6</sup> The PSE states

<sup>1</sup> 15 U.S.C. 78s(b)(1) [1988].

<sup>2</sup> 17 CFR 240.19b-4 [1991].

<sup>3</sup> A complete list of the PSE's fees applicable to the listing process is contained in the Listing Fees Schedule and is available at the Exchange's Listings Marketing Department.

<sup>4</sup> The \$2,500 fee applies to secondary issues regardless of whether the common stock is listed on the PSE. For example, an original listing of warrants on ABC stock will cost \$2,500, whether or not ABC common stock is listed on the PSE.

<sup>5</sup> Substitution may be required as a result or reincorporation, change of state of incorporation, a reverse stock split and other such events.

<sup>6</sup> The PSE does not propose to change the \$2,500 fee for secondary issues (i.e., preferred stock, warrants, bonds and rights).

<sup>1</sup> 15 U.S.C. 78s(b)(1) [1988].

<sup>2</sup> The proposed rule change filed on October 16, 1990 by the NASD and published in the Federal Register, originally requested that Article III, section 5(b), Article IV, sections 3 and 4 of the NASD By-Laws, and Article IV, section 5 of the NASD Rules of Fair Practice also be amended. These provisions are being reviewed but in the interim the NASD has requested that the Commission approve the proposed amendments to Article V, sections 1 and 3.

<sup>3</sup> Amendment No. 1 to the proposal, filed with the Commission on November 12, 1990, sets forth the results of the member vote on SR-NASD-90-53.

<sup>4</sup> See Securities Exchange Act Release No. 28554 (October 16, 1990); 55 FR 42925 (October 24, 1990).



that this fee would be comparable to that of the Midwest Stock Exchange ("MSE") and substantially lower than those charged by the New York Stock Exchange, the American Stock Exchange ("Amex") and the National Association of Securities Dealers, Inc. NASDAQ/National Market System ("NMS"). Additionally, the PSE proposes to raise the annual maintenance fee for additional issues from \$250 to \$500 as well as the annual maximum charge for maintenance fees from \$3,000 to \$5,000.<sup>7</sup> The PSE states that these increases are competitive with the fees charged by the MSE, the Philadelphia Stock Exchange ("Phlx") and the Boston Stock Exchange ("BSE"). Both the original listing fee for common stock as well as the annual maintenance fee for additional issues have not been amended since 1987.<sup>8</sup> In this regard, the PSE seeks to adjust these fees to more accurately reflect the costs of the listing and monitoring processes.

In addition, the Exchange is proposing to adopt two new fees. First, a listed company will incur a fee of \$250 for any change in its name or in the par value of its listed shares, which is made without a corresponding change in the amount of outstanding stock. This proposed fee is intended to recoup the Exchange's costs in processing these changes. The PSE asserts that this fee is the same as that charged by the BSE, and is nominally higher than that imposed by the Phlx.

Second, the Exchange proposes to adopt a non-refundable processing fee of \$250 for each original listing application for common stock. The Exchange states that the amount of this fee will be credited towards the applicant issuer's total listing entry fee if the application is approved. For example, an applicant who succeeds in attaining listing approval would only be required to pay the original listing fee minus the proposed processing fee already paid. If an application is withdrawn or disapproved, the applicant would have the opportunity to reapply within one year without paying another processing fee. The Exchange proposes to retain the discretion to waive all or any part of the proposed processing fee.

Presently, the PSE's Listing Agreement with issuing corporations provides that 25% of the original listing fee shall be retained by the Exchange in the event

the listing application is not approved.<sup>9</sup> If the application is resubmitted within one year, this service charge would be credited toward the listing fee. The PSE indicates that, historically, the listing fee has not been paid until the issuer's application was approved.

Consequently, in cases where an application has been disapproved (approximately 50% of the time), the issuer frequently has not paid any fee. Because no fee was collected, the PSE was not able to retain 25% of the fee, and no service charge revenue was derived.

The PSE states that the costs of processing these applications are significant, given the number of applications (approximately 50 per year) and the complexity of the issues that may require resolution. The PSE believes a processing fee will provide all applicant issuers with an economic incentive to determine that their company meets the minimum listings qualifications and is worthy of consideration prior to applying for inclusion on the Exchange. The PSE believes that changes to the application processing fee structure are necessary and appropriate to cover the costs associated with processing these applications. The PSE asserts that \$250 is comparable to the amount charged by the Amex and substantially less than imposed by NASDAQ.

While the overall effect of all of the above proposed changes is to increase listing fees, the PSE believes that such changes are necessary to offset rising costs associated with maintaining listing services and related overhead expenses. The PSE states that the rate changes will be competitive with those currently charged by other exchanges.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 6.<sup>10</sup> Specifically, the Commission believes the proposal is consistent with the section 6(b)(4) requirements that the rules of an exchange be designed to assure the equitable allocation of reasonable fees, dues and other charges

among members, issuers, and other persons using the Exchange's facilities.<sup>11</sup> The Commission believes that the proposed increases in listing fees are equitable because the increases should not result in an excessive allocation of PSE fees on its issuers as opposed to members and other persons using its facilities. The Commission further finds that the fees reasonable because the Exchange is proposing the increases as well as the new fees in order to offset rising costs in these areas.

The Exchange has stated that the proposed increases are competitive with and similar to fees charged by other exchanges. The Commission believes that improving the overall competitiveness of the Exchange vis-a-vis the other exchanges is consistent with the requirement in section 6(b)(5) that the rules of an exchange should be designed to remove impediments to and perfect the mechanism of a free and open market.<sup>12</sup> Accordingly, the Commission believes that it is appropriate to approve the proposed rule change.

*It is Therefore Ordered*, Pursuant to section 19(b)(2) of the Act,<sup>13</sup> that the proposed rule change (SR-PSE-91-29) is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.<sup>14</sup>

Margaret H. McFarland,  
Deputy Secretary.

[FR Doc. 91-26824 Filed 11-6-91; 8:45 am]  
BILLING CODE 8010-01-M

[Rel. No. IC-18389; 811-4522]

#### **T. Rowe Price Institutional Trust; Application for Deregistration**

November 1, 1991.

**AGENCY:** Securities and Exchange Commission ("SEC").

**ACTION:** Notice of application for deregistration under the Investment Company Act of 1940 ("Act").

**APPLICANT:** T. Rowe Price Institutional Trust.

Relevant Act Section: Section 8(f).

**SUMMARY OF APPLICATION:** Applicant seeks an order declaring that it has ceased to be an investment company.

**FILING DATE:** The application on Form N-8F was filed on May 31, 1991 and amended on October 7, 1991.

<sup>11</sup> 15 U.S.C. 78f(b)(4) (1988).

<sup>12</sup> 15 U.S.C. 78f(b)(5) (1988).

<sup>13</sup> 15 U.S.C. 78s(b)(2) (1988).

<sup>14</sup> 17 CFR 200.30-3(a)(12) (1991).

<sup>7</sup> The PSE does not propose to change the \$1,000 annual maintenance fee for a first issue (usually common stock) listed on the Exchange.

<sup>8</sup> See Securities Exchange Act Release No. 24123 (February 20, 1987), 52 FR 6641 (March 4, 1987) (notice of filing and immediate effectiveness of File No. SR-PSE-86-29).

<sup>9</sup> With respect to an original listing application for common stock, the Exchange is proposing to replace this 25% retention provision with the proposed processing fee. The PSE notes that 25% of the listing fee for subsequent listings of additional shares, substitutions of an original listing and secondary issue listings will still be retained. See letter from David P. Semak, Vice President, PSE, to Mary N. Revell, Branch Chief, Division of Market Regulation, SEC, dated October 28, 1991.

<sup>10</sup> 15 U.S.C. 78f (1988).



**HEARING OR NOTIFICATION OF HEARING:**

An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on November 26, 1991, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

**ADDRESSES:** Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicant, 100 East Pratt Street, Baltimore, Maryland 21202.

**FOR FURTHER INFORMATION CONTACT:**

Barry A. Mendelson, Staff Attorney, at (202) 504-2284, or Barry D. Miller, Branch Chief, at (202) 272-3018 (Division of Investment Management, Office of Investment Company Regulation).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

**Applicant's Representations**

1. Applicant is an open-end diversified management investment company organized as a Massachusetts business trust. On June 19, 1986, applicant filed a notification of registration on Form N-8A pursuant to section 8(a) of the Act and a registration statement on Form N-1A under the Securities Act of 1933. The registration statement was declared effective on August 11, 1986, and applicant's initial public offering commenced that same day.

2. As of the close of business on December 11, 1990, the net asset value of applicant was \$5,826,612.34. On December 12, 1990, all public security holders received distributions in cash equal to the net asset value of their shares of beneficial interest. Such distributions amounted to \$5,722,813.69. The remaining security holder, T. Rowe Price Associates, Inc., applicant's investment manager, redeemed its shares for their net asset value on December 13, 1990 and absorbed applicant's unamortized organizational expenses of \$714.

3. On November 6, 1990, the possibility that applicant would be dissolved was discussed with the board of trustees. The distributions of cash on

December 12-13, 1990 were made pursuant to that discussion. On January 15, 1991, applicant's board of trustees unanimously approved the liquidation and dissolution of applicant.

4. All portfolio securities were disposed of either through maturity of the security or by exercising the demand feature of the security. In all cases, the price received was equal to the par value of the security and no brokerage commissions were generated by the disposition.

5. Applicant is responsible for all expenses, fees, and other charges relating to the liquidation. As of the date of the amended application, the only such expenses have been legal expenses totalling approximately \$1,250.

6. As of the date of the amended application, applicant had no shareholders, assets, or liabilities. Applicant is not a party to any litigation or administrative proceeding. Applicant is not presently engaged in, or does it propose to engage in, any business activities other than those necessary for the winding up of its affairs.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,  
*Deputy Secretary.*

[FR Doc. 91-26923 Filed 11-6-91; 8:45 am]

BILLING CODE 8010-01-M

**DEPARTMENT OF STATE****Office of the Secretary****[Public Notice 1519]****Determination Under Section 513 of the Foreign Operations, Export Financing, and Related Programs Appropriation Act, 1991**

Pursuant to the authority vested in me by section 513 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1991 (Pub. L. 101-513), Public Law 102-109, and section 1-201 (a)(28) of Executive Order 12163, I hereby determine that subsequent to the termination of assistance for Suriname, a democratically elected government has taken office.

This determination shall be reported to the Congress and published in the Federal Register.

Dated: October 28, 1991.

James A. Baker III,  
*Secretary of State.*

[FR Doc. 91-26904 Filed 11-6-91; 8:45 am]

BILLING CODE 4710-10-M

**[Public Notice 1518]****Determination Under Section 4(a) of the International Narcotics Control Act of 1990**

Pursuant to the authority vested in me by section 4(a) of the International Narcotics Control Act of 1990 and Presidential Determination No. 91-20, dated January 25, 1991, I hereby determine the following:

(1) Bolivia, Colombia and Ecuador are implementing programs to reduce the flow of cocaine to the United States in accordance with a bilateral or multilateral agreement, to which the United States is a party, that contains specific, quantitative and qualitative performance criteria with respect to those programs;

(2) The armed forces and law enforcement agencies of Bolivia, Colombia and Ecuador are not engaged in a consistent pattern of gross violations of internationally recognized human rights, and the governments of those countries have made significant progress in protecting internationally recognized human rights, particularly in—

(A) Ensuring that torture, cruel, inhuman, or degrading treatment or punishment, incommunicado detention or detention without charges and trial, disappearances, and other flagrant denials of the right to life, liberty or security of the person are not practiced; and

(B) Permitting an unimpeded investigation of alleged violations of internationally recognized human rights, including providing access to places of detention, by appropriate international organizations (including nongovernmental organizations such as the International Committee of the Red Cross) or groups acting under the authority of the United Nations or the Organization of American States; and

(3) The Governments of Bolivia, Colombia and Ecuador have effective control over police and military operations related to counternarcotics and counterinsurgency activities.

James A. Baker, III,  
*Secretary of State.*

[FR Doc. 91 26816 Filed 11-6-91 8:45 am]

BILLING CODE 4710-10-m



## Bureau of Oceans and International Environmental and Scientific Affairs

[Public Notice 1517]

### U.S. MAB: Request for Proposals for Environmental Education Projects

The United States Man and the Biosphere (U.S. MAB) Program hereby announces its request for proposals to continue its assistance to the U.S. Peace Corps in the development of a worldwide environmental project initiative as described below.

U.S. MAB will accept proposals of a maximum length of 5 pages which outline how the objectives described below could be accomplished. A curriculum vitae (c.v.) of a maximum length of four pages for each principal which clearly demonstrates a history of competency in the implementation of such tasks must accompany the proposal. Proposals may not request more than the sum of forty-nine thousand two hundred dollars (\$49,200) to implement this initiative. All proposals must specify that all tasks will be completed within a maximum twelve month time frame. Payments will be made on a quarterly basis in equal installments.

All proposals and accompanying documents must be received by the U.S. MAB Secretariat no later than the close of business (COB) November 18, 1991. Proposals and c.v.s. will be evaluated on the basis of criteria noted in the following section and on the past performance competence of the proposed principal(s).

Selection will be made during the last week of November. The candidate principal(s) must be prepared to implement their proposal on or about December 2, 1991, if selected.

Proposals should be sent to: U.S. MAB Secretariat, room 608, SA-37, OES/EGC/MAB, U.S. Department of State, Washington, DC 20522-3706.

#### Objective II (Peace Corps Worldwide Environmental Education Projects Initiative)

Assist in development of a Peace Corps worldwide environmental projects initiative through a funding mechanism for providing technical assistance, including but not limited to:

- Further develop the ongoing collaboration with the Environment Sector in the design of Environmental Education projects and project components. As part of this effort, develop and coordinate in-service training workshops in Education and the Environment for mathematics and science volunteers and their

counterparts in countries which are requesting this assistance.

- Take primary responsibility for providing technical support to Peace Corps math and science projects, including, but not limited to, the following activities:

- Manage the ongoing collaboration between the Education Sector and Teachers College of Columbia University (TCCU), and provide technical assistance to enable TCCU to deliver high quality workshops for math and science volunteers and their counterparts.

- Undertake approximately for consultancies to respond to requests from Peace Corps posts for technical assistance in project development, training development, or project evaluation.

- Develop and manage other initiatives in math/science, including, but not limited to, collaboration with other governmental and private agencies offering assistance to Peace Corps in project development and training.

- Review/select materials to be distributed through Peace Corps' Information Collection and Exchange (ICE).

- Initiate and manage the development of training manuals and materials.

- Support the agency in the implementation of PATS (Programming and Training System), including project design, monitoring, and evaluation assistance. In addition, collaborate with incumbent Sector Specialists in the following tasks:

- Participate in project plan reviews for Education projects;

- Undertake annual reviews of country programs and technical assistance requests; and

- Coordinate consultancies to respond to programming and training requests for the field, including developing and managing budgets and hiring and managing consultants.

- Work with other Education Sector specialists in regular sector activities, including, but not limited to:

- Initiating and maintaining collaborative relationships with private organizations and other government agencies;

- Preparing documentation of sector activities;

- Sharing administrative tasks of the sector including managing budgets and coordinating activities; and

- Collaboration with other sectors in OTAPS (Office of Training and Program Support); for example, incorporating attention to WID (Women in Development) and youth issues into Education sector projects/

activities and with other offices in the Peace Corps.

In addition to U.S. MAB evaluation criteria, the following criteria should also be applied to proposals:

- Demonstrated ability of the proposer to design and deliver training for environmental education.

- Demonstrated ability of the proposer to manage budgets and personnel.

- Demonstrated ability of the proposer to conduct needs assessments and develop project designs.

- Fluency in French or Spanish preferred.

For further information please contact: Roger E. Soles, Executive Director, U.S. MAB, (703) 235-2946.

Dated: October 28, 1991.

Roger E. Soles,  
Executive Director, U.S. Man and the Biosphere Program, Office of Global Change.  
[FR Doc. 91-26815 Filed 11-6-91; 8:45 am]

BILLING CODE 4710-09-M

## TENNESSEE VALLEY AUTHORITY

### Paperwork Reduction Act of 1980, as Amended by Public Law 99-591; Information Collection Under Review by the Office of Management and Budget (OMB)

**AGENCY:** Tennessee Valley Authority.

**ACTION:** Information collection under review by the Office of Management and Budget (OMB).

**SUMMARY:** The Tennessee Valley Authority (TVA) has sent to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), as amended by Public Law 99-591.

Requests for information, including copies of the information collection proposed and supporting documentation, should be directed to the Agency Clearance Officer whose name, address, and telephone number appear below. Questions or comments should be made within 30 days directly to the Agency Clearance Officer and also to the Desk Officer for the Tennessee Valley Authority, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503; Telephone: (202) 395-3084.

Agency Clearance Officer: Mark R. Winter, Tennessee Valley Authority, 1101 Market Street (EB 4B), Chattanooga, TN 37402-2801; (615) 751-2523.

Type of Request: Regular submission.



*Title of Information Collection:*  
Residential Energy Services Program.  
*Frequency of Use:* On occasion.  
*Type of Affected Public:* Individuals  
or households.

*Small Businesses or Organizations  
Affected:* No.

*Federal Budget Functional Category  
Code:* 271.

*Estimated Number of Annual  
Responses:* 12000.

*Estimated Total Annual Burden  
Hours:* 3600.

*Estimated Average Burden Hours Per  
Response:* 3.

*Need For and Use of Information:* This  
information is used by distributors of  
TVA power to assist in identifying and  
financing energy improvements for their  
electrical energy customers.

## DEPARTMENT OF THE TREASURY

### Federal Law Enforcement Training Center; Rechartering of the Advisory Committee to the National Center for State and Local Law Enforcement Training

**AGENCY:** Federal Law Enforcement  
Training Center, Department of the  
Treasury.

**ACTION:** Notice of determination of  
necessity for renewal of the Advisory  
Committee to the National Center for  
State and Local Law Enforcement  
Training.

**SUMMARY:** It is in the public interest to  
continue the existence of the Advisory  
Committee to the National Center for  
State and Local Law Enforcement  
Training.

The Federal Law Enforcement  
Training Center (FLETC), Department of  
the Treasury, pursuant to the Federal  
Advisory Committee Act of October 6,  
1972, Public Law 92-463, as amended,

and with approval of the Secretary of  
the Treasury, announces the renewal of  
the Charter of the Advisory Committee  
to the National Center for State and  
Local Law Enforcement Training. This  
determination follows consultation with  
the Committee Management Secretary,  
General Services Administration.

#### Purpose

The primary purpose of the committee  
is to provide a forum for discussion and  
interchange between a broad cross-  
section of representatives for the law  
enforcement community and related  
training institutions on training issues  
and needs. Considering that there are  
over 40,000 individual police  
departments throughout the country, the  
advice emanating from this exchange is  
very important to the Director of the  
Federal Law Enforcement Training  
Center and the Director of the National  
Center for State and Local Law  
Enforcement Training (National Center).  
The committee's advice is critical to  
ensuring that programs developed and  
offered by the National Center are  
meeting the unique and specialized  
needs of the State and local law  
enforcement community and enhancing  
the networking between Federal, State  
and local agencies. This networking is  
essential to an efficient and effective  
overall system.

Although FLETC representatives  
participate in the training committee  
activities of the major police  
membership associations, no forum  
exists which provides the broad  
representation required to meet the  
needs of the National Center. The  
uniqueness of the program requires an  
appropriately selected and specifically  
dedicated group.

The committee advises the Director of  
FLETC and the Director of the National  
Center for State and Local Law

Enforcement Training on policy  
formulation, training needs, curriculum  
and course content, student admission  
and evaluation. There is no question  
that the committee's input has been very  
instrumental in the successes enjoyed to  
this point. Resources have been  
committed only to those programs which  
meet unique needs of the State and local  
law enforcement community. All  
programs are well attended, and  
critiques and evaluations are quite  
positive. In addition, State and local  
agencies have actively participated in  
the development and delivery of the  
programs by providing personnel as  
subject matter experts, course  
developers and instructors. The  
programs offered have been developed  
only after a thorough screening process  
to ensure that the limited resources  
available are being committed most  
productively.

The committee does not duplicate  
functions being performed within  
Treasury or elsewhere in the Federal  
government.

*Termination Date:* The services of the  
committee are expected to be needed for  
an indefinite period of time. No  
termination date has been established  
which is less than two years from the  
date the charter is filed.

Accordingly, I hereby determine,  
pursuant to the provisions of the Federal  
Advisory Committee Act, Public Law  
92-463, as amended, that continuation of  
the Advisory Committee to the National  
Center for Local Law Enforcement  
Training for a two-year period, is in the  
public interest.

Dated: November 1, 1991.

David M. Nummy,

Acting Assistant Secretary (Management).  
[FR Doc. 91-26910 Filed 11-6-91; 8:45 am]

BILLING CODE 4810-25-M



# Sunshine Act Meetings

Federal Register

Vol. 56, No. 216

Thursday, November 7, 1991

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

## NATIONAL CREDIT UNION ADMINISTRATION

### Notice of Change in Subject of Meeting

The National Credit Union Administration Board determined that its business requires that the previously announced closed meeting (Federal Register, Vol. 56, No. 211, Thursday, October 31, 1991, page 56115) scheduled for 9:30 a.m. on Tuesday, November 5, 1991, include the following additional item, which is closed to public observation:

Administrative Action under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).

The Board voted unanimously to add this item to the closed agenda.

The previously announced item was:

1. Agency Office Space. Closed pursuant to exemptions (2), (4), and (9)(B).

**FOR MORE INFORMATION CONTACT:** Becky Baker, Secretary of the Board, Telephone (202) 682-9600.

Ruby Baker,

*Secretary of the Board.*

[FR Doc. 91-27044 Filed 11-5-91; 3:37 pm]

BILLING CODE 7535-01-M

## NATIONAL CREDIT UNION ADMINISTRATION

### Notice of Meetings

**TIME AND DATE:** 9:30 a.m., Wednesday, November 13, 1991.

**PLACE:** Filene Board Room, 7th Floor, 1776 G Street, N.W., Washington, D.C. 20456.

**STATUS:** Open.

### BOARD BRIEFINGS:

1. Economic Commentary.
2. Central Liquidity Facility Report and Review of CLF Lending.
3. Insurance Fund Report.

### MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Open Meeting.
2. Proposed Rule: Part 704, NCUA's Rules and Regulations, Corporate Credit Union.
3. Fiscal Year 1992 Operating Fee Assessment.
4. Agency Office Space.

**RECESS:** 10:45 a.m.

**TIME AND DATE:** 11:00 a.m., Wednesday, November 13, 1991.

**PLACE:** Filene Board Room, 7th Floor, 1776 G St., N.W., Washington, D.C. 20456.

**STATUS:** Closed.

### MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Closed Meeting.
2. Administrative Action under Sections 116 and 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii) and (9)(B).
3. Administrative Actions under Section 206 of the FCU Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
4. Administrative Action under Sections 206 and 208 of the FCU Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
5. Administrative Action under Section 207 of the FCU Act. Closed pursuant to exemptions (4), (6), and (8).
6. Personnel Policies. Closed pursuant to exemptions (2) and (6).

**FOR MORE INFORMATION CONTACT:** Becky Baker, Secretary of the Board, Telephone (202) 682-9600. NATIONAL CREDIT UNION ADMINISTRATION 7535-01

Becky Baker,

*Secretary of the Board.*

[FR Doc. 91-27045 Filed 11-5-91; 3:37 pm]

BILLING CODE 7535-01-M

## BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

**TIME AND DATE:** 11:00 a.m., Tuesday, November 12, 1991.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets NW., Washington, DC 20551.

**STATUS:** Closed.

### MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

### CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: November 4, 1991.

Jennifer J. Johnson,

*Associate Secretary of the Board.*

[FR Doc. 91-26988 Filed 11-5-91; 4:47 pm]

BILLING CODE 6210-01-M







# Test Report

Thursday  
November 7, 1991

## Part II

## Department of Labor

Occupational Safety and Health  
Administration

29 CFR Parts 1910, 1915 and 1926  
Occupational Exposure to Methylene  
Chloride; Proposed Rule



## DEPARTMENT OF LABOR

## Occupational Safety and Health Administration

29 CFR Parts 1910, 1915 and 1926

[Docket No. H-71]

RIN 1218-AA98

## Occupational Exposure to Methylene Chloride

**AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.

**ACTION:** Proposed rule.

**SUMMARY:** The Occupational Safety and Health Administration (OSHA) proposes to amend its existing regulation for employee exposure to methylene chloride (MC, also known as methylene dichloride, dichloromethane or DCM). The Assistant Secretary has determined, based on animal and human data, that the current permissible exposure limits (PELs) do not adequately protect employee health. OSHA proposes to reduce the existing 8-hour time-weighted average (TWA) exposure from 500 parts MC per million parts of air (500 ppm) to 25 parts per million. The Assistant Secretary also proposes to delete the existing ceiling limit concentration of 1,000 ppm and proposes to reduce the existing short-term (5 minutes in any 2 hours as a maximum peak concentration) exposure limit (STEL) from 2,000 ppm to 125 ppm, measured as a 15-minute TWA. In addition, the Agency proposes to set an "action level" of 12.5 ppm, measured as an 8-hour TWA, in order to minimize the compliance burden for employers whose employees have consistently very low exposure to MC. The proposal also contains provisions for exposure control, personal protective equipment, employee exposure monitoring, training, medical surveillance, hazard communication, regulated areas, emergency procedures and recordkeeping.

Two of the considerations which may affect OSHA's final PELs for MC are the impact of pharmacokinetic data on OSHA's current risk estimates and the impact of Title III of the Clean Air Act Amendments of 1990 on the MC industry profile. OSHA is soliciting information on pharmacokinetics (Issue 6) and on the potential impacts of the Clean Air Act Amendments (Issue 9). Based on its review of the data in the record, including the information received in response to the above cited issues, OSHA may promulgate PELs which differ from those proposed. The final

PELs may vary from those proposed by as much as a factor of five. Examples of federal agencies which have used pharmacokinetic data to reduce risk estimates from those originally calculated are the EPA, which decreased that Agency's risk estimates by a factor of 8.8, and the Consumer Product Safety Commission, which found that the pharmacokinetic data would support lowering the risk estimates by a factor of 2.2 compared to their original risk estimates.

This proposed standard applies to all employment in general industry, shipyards, longshoring and construction.

**DATES:** Comments concerning the proposed standard must be postmarked on or before April 6, 1992.

**ADDRESSES:** Comments are to be submitted in quadruplicate to: The Docket Office, Docket No. H-71, room N-2634, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone No. (202) 523-7894.

Comments limited to 10 pages or less in length also may be transmitted by facsimile to (202) 523-5046 or 8-523-5046 (for FTS), provided that the original and 3 copies of the comment are sent to the Docket Officer thereafter.

**FOR FURTHER INFORMATION CONTACT:** Mr. James F. Foster, OSHA Office of Public Affairs, United States Department of Labor, room N-3641, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 523-8151.

**SUPPLEMENTARY INFORMATION:****Information Collection Requirements:**

5 CFR part 1320 sets forth procedures for agencies to follow in obtaining OMB clearance for information collection requirements under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. This proposed MC standard requires the employer to allow OSHA access to records. In accordance with the provisions of the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA certifies that it has submitted the information collection requirements for this proposal to OMB for review under section 3504(h) of that Act.

Public reporting burden for this collection of information is estimated to average five minutes per response. Send any comments regarding this burden estimate, or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Information Management, Department of Labor, room N-1301, 200 Constitution Avenue, NW., Washington, DC 20210; and to the Office of Information and Regulatory Affairs,

Office of Management and Budget, Washington, DC 20503.

**I. General**

The preamble to the proposed standard on occupational exposure to Methylene Chloride (MC) discusses events leading to the proposal, physical and chemical properties of MC, manufacture and use of MC, health effects of exposure, degree and significance of the risk presented, an analysis of the technological and economic feasibility, regulatory impact and regulatory flexibility analysis, and the rationale behind the specific provisions set forth in the proposed standard. The discussion follows this outline:

- I. General
- II. Pertinent Legal Authority
- III. Events Leading to the Proposed Standard
- IV. Request for Information
- V. Chemical Identification, Production Technologies and Industrial Uses
  - A. Chemical Identification
  - B. Production Technologies and Industrial Uses
    1. MC Production
    2. Polyurethane Foam Blowing
    3. Aerosols
    4. Polycarbonate Resin
    5. Pharmaceuticals
    6. Manufacturing of Paint and Paint Removers/Strippers
    7. Paint Stripping
    8. Degreasing and Metal Cleaning
    9. Cellulose Triacetate Fiber and Cellulose Triacetate Photographic Film Production
    10. Electronics
    11. Miscellaneous Usages (Food extraction, Ink use, Pesticide Manufacturing, Solvent Recovery and Other uses)
- VI. Technological Feasibility Assessment of Engineering Controls to Reduce Employees' Exposures
  - A. MC Production
  - B. Polyurethane Foam Blowing
  - C. Aerosols
  - D. Polycarbonate Resin
  - E. Pharmaceuticals
  - F. Manufacturing of Paint and Paint Removers/Strippers
  - G. Paint Stripping
  - H. Degreasing and Metal Cleaning
  - I. Cellulose Triacetate Fiber and Film Base Production
  - J. Electronics
  - K. Miscellaneous Usages (Food extraction, Pesticide formulation, Solvent recovery, and Ink manufacture)
- VII. Health Effects
  - A. Introduction
  - B. Disposition and metabolism of MC
    1. Absorption and distribution of MC
    2. Metabolism of MC
  - C. Carcinogenicity
    1. Animal studies
      - a. Mouse studies
      - b. Rat studies
      - c. Hamster studies
    2. Summary of animal studies
    2. Epidemiologic studies



- a. Studies of fiber production workers
- b. Studies of film production workers
- c. Summary of epidemiological studies
- 3. Mutagenicity studies
  - a. Bacterial studies.
  - b. Yeast and Drosophila studies
  - c. Studies in mammalian cells
  - d. Summary of mutagenicity studies
- D. Other toxic responses
  - 1. CNS toxicity
    - a. Animal studies
    - b. Human studies
  - c. Summary of CNS toxicity studies
  - 2. Cardiac toxicity
    - a. Animal studies
    - b. Human studies
  - c. Summary of cardiac toxicity
  - 3. Hepatic toxicity
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Appendix A: Substance Safety Data Sheet and Technical Guidelines for Methylene Chloride

Appendix B: Medical Surveillance for Methylene Chloride

Appendix C: Qualitative and Quantitative Fit Testing Procedures for Respirators

## II. Pertinent Legal Authority

This proposed standard and issuance of a final standard is authorized by sections 6(b), 8(c), and 8(g)(2) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655(b), 657(c) and 657(g)(2). Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. It states:

The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

Section 3(8) defines an occupational safety and health standard as "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." The Supreme Court has held under the Act that the Secretary, before issuing any new standard, must determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment, *Industrial Union Department v. American Petroleum Institute*, 488 U.S. 607 (1980). The Court stated that " \* \* \* before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (488 U.S. at 642). The Court also stated "that the Act does limit the Secretary's power to require the elimination of significant risks" (488 U.S. at 644, n. 49).

The Court indicated however, that the significant risk determination is "not a mathematical straitjacket." The Court stated that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty." The Court ruled that "a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge," [and that] "the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (488 U.S. at 655, 656). The Court also stated that "while the Agency must support its finding that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations". (488 U.S. at 655, 656 n. 62).

After OSHA has determined that a significant risk exists and that such a risk can be reduced or eliminated by the proposed standard, it must set a standard "which most adequately assures, to the extent feasible on the basis of the best available evidence, that no employees will suffer material impairment of health \* \* \* section 6(b)(5) of the Act. The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility, *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is" (452 U.S. at 509). The Court stated that the Agency could use cost-effectiveness analysis and choose the least costly of two equally effective standards (452 U.S., 531, n. 32).

Section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." Section 8(g)(2) gives the Secretary authority to "prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under this Act."

In addition, the Secretary's responsibilities under the Act are amplified by its enumerated purposes which include:

Encouraging employers and employees in their efforts to reduce the number of occupational safety and



health hazards at their places of employment and stimulating employers and employees to institute new programs and to perfect existing programs for providing safe and healthful working conditions [29 U.S.C. 651(b)(1)];

Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to business affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under the Act: [29 U.S.C. 651(b)(3)];

Building upon advances already made through employer and employee initiative for providing safe and healthful working conditions [29 U.S.C. 651(b)(4)];

Providing for the development and promulgation of occupational safety and health standards [29 U.S.C. 651(b)(9)] and providing for appropriate reporting procedures which will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem [29 U.S.C. 651(b)(12)].

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions [29 U.S.C. 651(b)(6)];

Encouraging joint labor-management efforts to reduce injuries and diseases arising out of employment [29 U.S.C. 651(b)(13)]; and

Developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems [19 U.S.C. 651(b)(5)].

Because the MC standard is reasonably related to these statutory goals, and the Agency's judgment is that the evidence satisfies the statutory requirements, and because the proposed standard is feasible and substantially reduces a significant risk of cancer and other adverse health effects, the Secretary preliminarily finds that the proposed standard is necessary and appropriate to carry out her responsibilities under the Act.

### III. Events Leading to the Proposed Standard

The present OSHA standard for MC requires employers to assure that employee exposure does not exceed 500 ppm as an 8-hour TWA, 1000 ppm as a ceiling concentration, and 2000 ppm as a maximum peak for a period not to exceed 5 minutes in any 2 hours (29 CFR 1910.1000, Table Z-2). This standard was adopted by OSHA in 1971 pursuant to section 6(a) of the OSH Act, 29 U.S.C. 655, from an existing Walsh-Healey Federal Standard. The source of this

Walsh-Healey Standard (Ex. 7-1) was the American National Standards Institute (ANSI) standard for acceptable concentrations of MC (ANSI—Z37.23-1969), which were intended to protect workers from injury to the neurological system including loss of awareness and functional deficits linked to anesthetic and irritating properties of MC which had been observed from excessive, acute or large chronic exposures to MC in humans and experimental animals.

In 1946, the American Conference of Governmental Industrial Hygienists (ACGIH) recommended a Threshold Limit Value (TLV) of 500 ppm for MC (Ex. 2). In 1975, the ACGIH lowered the recommended TLV to 100 ppm (Ex. 7-11).

In March 1976, the National Institute for Occupational Safety and Health (NIOSH) published "Criteria for a recommended standard for Methylene Chloride" (Ex. 2), which recommended a reduction of the occupational exposures to MC to 75 ppm as an 8-hour TWA, and a lower peak exposure not to exceed 500 ppm. Further exposure reduction based on the ambient level of carbon monoxide was also recommended.

In 1984, the International Labor Office-Geneva (Ex. 7-50) listed MC standards for Romania, Poland and the USSR as 145, 14.5, and 14.5 ppm (500, 50 and 50 mg/m<sup>3</sup>), respectively.

In February 1985, the National Toxicology Program (NTP) reported the final results of animal studies indicating that MC is a potential cancer causing agent (Ex. 7-008). Subsequently, the Environmental Protection Agency (EPA), upon receipt of the NTP studies, initiated a risk assessment evaluation to determine whether or not MC presents an unreasonable risk to human health or environment and to determine if regulatory actions are needed to eliminate or reduce exposures.

On May 14, 1985, EPA announced its determination that MC was a probable human carcinogen. EPA classified MC as Group B2, in accordance with its interim guidelines for cancer risk (49 FR 46294), and hence announced the initiation of a 180-day priority review (50 FR 20126) under section 4(f) of the Toxic Substances Control Act (TSCA). In meeting its mandate under section 4(f) of TSCA to initiate a regulatory action, on October 17, 1985, EPA published an Advance Notice of Proposed Rulemaking (ANPR) (50 FR 42037) for the purpose of collecting the necessary information required for initiating a rulemaking. In this notice, EPA established December 16, 1985, as its deadline for receiving comments.

On April 11, 1985, the U.S. Consumer Product Safety Commission (CPSC)

released its risk assessment findings for MC and began to consider a regulatory action to ban MC containing products and to develop a voluntary hazard communication program for consumers.

On December 18, 1985, the U.S. Food and Drug Administration (FDA) published a proposal to ban the use of MC as an ingredient in aerosol cosmetic products (50 FR 51551). This proposal was based on a risk assessment that used the NTP animal data.

On July 19, 1985, Owen Bieber, President of International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), petitioned OSHA to act expeditiously on reducing workers' exposure to MC. Specifically, Mr. Bieber requested that: (1) OSHA publish a hazard alert; (2) OSHA issue an emergency temporary standard (ETS); and (3) OSHA begin work on a new permanent standard for controlling MC exposure. Subsequently, the following unions joined UAW in petitioning OSHA to act on revising the current standard:

- A. International Union, Allied Industrial Workers of America;
- B. Glass, Pottery, Plastics and Allied Workers International Union;
- C. United Furniture Workers of America;
- D. The Newspaper Guild;
- E. Communication Workers of America; and
- F. United Steelworkers of America.

In March 1986, in preliminary response to the UAW petition, OSHA issued a "Guideline for Controlling Exposure to Methylene Chloride." This document was intended to provide information to employers and workers on risks and methods of controlling exposure (Ex. 8-11).

In April 1986, NIOSH published a Current Intelligence Bulletin #46 on MC reflecting the findings of the NTP study (Ex. 8-26). In it, NIOSH concluded that MC should be regarded as a potential occupational carcinogen and that exposure should be controlled to the lowest feasible level.

In May 29, 1986, the BNA Occupational Safety and Health Reporter published the announced intention of ACGIH to lower the TLV for Methylene Chloride (MC) from 100 ppm to 50 ppm and to classify MC as an A2 carcinogen (an industrial substance suspect of carcinogenic potential for man) (Ex. 8-27).

On August 20, 1986, the CPSC issued a proposed rule [51 FR 29778] "that would declare household products containing other than contaminant levels of MC to be hazardous substances." The CPSC noted the proposal was prompted by



evidence that inhalation of MC vapor increased the incidence of various malignant and benign tumors in rats and mice. Accordingly, the commission proposed to require that household products which can expose consumers to MC vapor be treated as hazardous substances and be labeled as provided by section 2 (p)(1) of the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261 (p)(1)). The FHSA requires the use of labels which (1) indicate that exposure to a product may present a cancer risk; (2) explain the factors (such as level and duration of exposure) that control the degree of risk; and (3) explain the precautions to be taken.

On November 17, 1986, OSHA notified the UAW that OSHA denied the request for an Emergency Temporary Standard, but agreed that work on a permanent standard should commence (Ex. 3A).

On November 24, 1986, OSHA announced, in an Advance Notice of Proposed Rulemaking (ANPR) [51 FR 42257], that it was considering revising the present occupational health standard for MC. The Agency based this action on animal studies which indicated the present standard may not provide adequate protection against potential cancer risks and other adverse health effects. The ANPR summarized OSHA's information regarding the production and use of MC, occupational exposure to MC, and the potential adverse health effects associated with MC exposure. In addition, the notice invited interested parties to submit comments, recommendations, data, and information on a variety of issues related to the regulation of MC. OSHA received 43 comments in response to the ANPR. Those comments are discussed in the appropriate sections of the proposal, below.

On December 5, 1986, the FDA reopened the comment period for 30 days on the above-cited proposal to ban the use of MC in cosmetic products [51 FR 43935]. The reopening enabled interested parties to submit comments on studies received after the close of the initial comment period regarding MC comparative pharmacokinetics, metabolism, and genotoxicity.

On September 14, 1987, the CPSC issued a statement of interpretation and enforcement policy, in lieu of continuing with rulemaking, which expressed the Commission's determination that consumer products containing MC and capable of exposing consumers to significant amounts of MC may pose cancer risk to humans and, therefore, are subject to the above-described hazardous substance labeling requirements. The CPSC explicitly retained the option of resuming the

rulemaking if voluntary compliance with and enforcement of the Commission's interpretation did not adequately induce firms to label their products appropriately.

While pursuing this course of action, OSHA has also been participating in an interagency committee to define regulatory needs for chlorinated solvents in general. This effort is being led by EPA, and it includes representatives from OSHA, FDA, and CPSC. Its focus is on manufacturing, use, and disposal of the highest volume chlorinated solvents, which may be used as substitutes for MC including, perchloroethylene, trichloroethylene, carbon tetrachloride, methyl chloroform, and CFC-113. All of these chemicals are considered to be toxic to humans or hazardous to the environment. Three of them have positive evidence of carcinogenicity. The interagency committee was created: (1) To avoid duplication and inconsistency among the several government agencies regulating chlorinated solvents; (2) to account for potential interchangeability among these solvents; and (3) to avoid transfer of risks from one medium—air, water, waste—or one population—workers, consumers, general public—to another as a result of piecemeal and uncoordinated regulation. All information derived from the interagency committee will be shared and incorporated into OSHA's docket on MC.

In 1988, ACGIH officially lowered the TLV for MC to 50 ppm as an 8-hour TWA.

On June 29, 1989, the FDA issued a final rule that banned the use of MC in cosmetic products [54 FR 27328]. The Agency based its final rule on scientific studies that showed inhalation of MC caused cancer in laboratory animals. The FDA concluded, accordingly, "that continued use of MC in cosmetic products may pose a significant risk to human health . . ." The Agency considered comments and information regarding the application of a physiologically-based pharmacokinetic model to the prediction of human cancer risk. The FDA determined that the risk assessment developed using animal studies should not be changed to reflect the "pharmacokinetic and metabolic data and hypothesized GST metabolic mechanism of carcinogenicity."

On August 8, 1990, the Consumer Product Safety Commission (CPSC) issued a General Order (55 FR 32282) that required manufacturers, importers, packagers and private labelers of consumer products containing 1% or more of MC to report to the CPSC information on the labeling and

marketing of those products. The CPSC indicated that the information obtained would aid the Commission in evaluating the CPSC's policy concerning the labeling of MC-containing products as hazardous substances, pursuant to the Federal Hazardous Substances Act.

#### IV. Request for Information and Comments

OSHA requests public comment on the information and proposed regulatory text presented in this NPRM and on other relevant issues. That input will assist the Agency in evaluating the proposed rule and in ensuring that the final rule sets appropriate requirements for protection of employees exposed to MC. OSHA requests that parties who suggest changes in proposed regulatory provisions include supporting information with their comments. OSHA also requests that interested parties who have MC-related health data not discussed in this notice submit that information to the Agency.

Comment is requested on the following issues:

1. Do the proposed provisions provide adequate protection for workers against all known hazards associated with exposure to MC?

2. Please provide information regarding the inclusion of provisions for medical examinations, respirators, personal protective clothing and equipment, work practices, emergencies, regulated areas, maintenance of records, employee information and training, and labels and signs. What form should such provisions take in the final standard? To what extent are these provisions currently being employed by industry and what are their costs?

3. Does OSHA's proposed 25 ppm standard for MC substantially eliminate significant risk and is it feasible and appropriate? Should a different exposure limit be set, and if so, what is the supporting evidence?

4. In order to further protect against adverse effects from worker exposure to MC, OSHA has proposed a 15-minute short term exposure limit (STEL) of 125 ppm. Please provide information and supporting data regarding the adequacy of the proposed STEL. Should OSHA promulgate a different STEL? If so, what evidence is available to support a different STEL?

5. Should OSHA set an action level for occupational exposure to MC? Is the proposed 12.5 ppm level appropriate? Should a different action level be set? If so, what evidence supports the suggested change? What provisions should be triggered by the action level?



6. In its current quantitative risk assessment, OSHA relied primarily on the NTP mouse bioassay to estimate the cancer risk to humans exposed to MC. OSHA determined that the NTP study provided the best available data for MC risk assessment, demonstrating a statistically significant carcinogenic dose response relationship. Continuing research on the metabolism of MC has elucidated some of the pharmacokinetic differences between rodents and humans. These data suggested that risks extrapolated from test animals to humans based on applied dose methods, such as those used by OSHA in this proposal, may have overestimated the human cancer risks.

The use of pharmacokinetic data in risk assessments requires that assumptions be made concerning the mechanism of carcinogenic action of MC. Furthermore, the incorporation of estimated values for a number of parameters in pharmacokinetic models may increase the uncertainties of the risk assessment results. These uncertainties and assumptions will be evaluated in light of new data collected during the rulemaking process.

The information acquired through the rulemaking will aid OSHA in resolving the uncertainties, and in determining if species differences should be incorporated into a pharmacokinetic model for estimating cancer risk to humans exposed to MC.

OSHA has serious concerns about the best utilization of the pharmacokinetic models in cancer risk assessments for MC. OSHA solicits comments and information on the following aspects of this issue:

(a) How can pharmacokinetics be best applied to the risk assessment of MC and what are the current limitations of this approach in the quantitation of health risks? What weight should OSHA give to pharmacokinetic data in its risk assessments and why?

(b) Given that five separate risk assessments have utilized the pharmacokinetic models for MC in five different ways (resulting in from 0 to 170 fold reduction in the final risk when compared with assessments not utilizing pharmacokinetic data), how can OSHA best utilize the existing pharmacokinetic data and still be certain of protecting worker health?

(c) Which parameters in the pharmacokinetic models are most sensitive to errors in measurement or estimation? Can an increased database reduce the uncertainties in these parameters?

(d) How much confidence can be placed in the human *in vitro* MC metabolism data, especially that for lung

tissue? How will human variability in these parameters affect the extrapolation of risk from rodent species?

(e) Are there any studies in progress which attempt to verify the predictive ability of the model *in vivo*, (i.e., by giving doses in a lifetime bioassay which will produce cancer in a species other than the B6C3F<sub>1</sub> mouse and the F344 and Sprague-Dawley rats)?

(f) OSHA recognizes the large areas of uncertainty which exist in applied dose risk assessment procedures. If pharmacokinetic modeling reduces these uncertainties, can the reduction in uncertainty be quantified? Are additional uncertainties introduced into the risk assessment process by the use of pharmacokinetic models?

(g) By using the pharmacokinetic models in the risk assessment process, one is making an assumption about the carcinogenic mechanism of action of methylene chloride. Are there any new studies on the carcinogenic mechanism of action of MC which would support or refute this assumption?

(h) If the carcinogenic process is, in fact, not the result of the metabolite(s) from the GST pathway alone, but is due to a combination of metabolites or a combination of the parent compound plus the metabolites, how would the pharmacokinetic model and the subsequent risk assessments be affected? Can these effects be quantified?

(i) One of the assumptions made in the pharmacokinetic model is that the target tissues for MC are liver and lung. Can this model predict cancer incidences at other sites? If not, is there a way to factor in consideration of possible MC-induced human cancers at other sites than liver and lung?

(j) OSHA solicits information supporting or refuting interspecies allometric scaling based on body weight or body surface area.

7. OSHA has noted in the Health Effects Section, below, that carbon monoxide is formed as a metabolite of MC in humans and that exposure to both MC and carbon monoxide may be more harmful than exposure to either substance alone. How should the standard deal with the effects of simultaneous occupational exposures to carbon monoxide and MC? Should the permissible exposure limit for MC be lower when exogenous carbon monoxide is present, as NIOSH has suggested? How should an air monitoring strategy deal with such exposures when combined?

8. Please submit any additional or updated epidemiological studies or updated information on exposures for

the employee populations in the studies OSHA has included in this proposal. Such information would be useful to the Agency in assessing the risk of occupational exposure to MC.

9. Title III of the Clean Air Act Amendments of 1990 (Pub. L. 101-549, 104 Stat. 2399) established a list of hazardous air pollutants (including MC) and required EPA to set emissions standards which "require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing sources \* \* \*." EPA has not yet determined how it will regulate MC emissions. Further, EPA has not developed any information on the extent and magnitude of MC use, including projection of any change in the current industry profile. Therefore, at this time, it is expected that EPA may take action which could impact the magnitude and the extent of MC use, including possible change in the industry profile (both number of firms and number of workers).

OSHA believes that, if engineering devices for the control of ambient emissions become more readily affordable and efficient, there will be a possibility of increasing MC usage because of its established performance qualities and desirable safety characteristics (low flammability). On the other hand, if compliance with the requirements of the Clean Air Act makes it less desirable for industry to continue the use of MC, some industries may abandon, either totally or partially, the use of MC. OSHA is interested in obtaining information or comments on the predicted impact of the Clean Air Act Amendments on the production, use and industry profile for MC. OSHA will use this information to determine how the Clean Air Act Amendments may change the overall population risk for MC exposure. OSHA will take into consideration any comments received regarding these impacts of the Clean Air Act Amendments in its preparation of the final RIA for MC.

10. What, if any, changes made to improve productivity or product quality in the way MC is produced or used, have also resulted in changes (reductions or increases) in worker exposures to MC?

11. In the printing industry, MC has been identified as a constituent of ink and the solvent used to clean the



printing plates (blanket wash). Current information indicates that MC use in ink formulation is being phased out through substitution. Because of the availability of a substitute for MC in ink formulation, OSHA has determined that it would be reasonable to project a similar decline or even elimination of MC use in blanket wash. OSHA is requesting public comments to verify the extent and magnitude of the current and future use of MC in blanket wash, if any.

12. Information gathered in response to the EPA call-in announcement indicates that MC usage in pesticides and in pesticide manufacture has already been, or is being, phased out. OSHA is soliciting information on the extent and magnitude of MC usage in pesticide manufacturing, if any.

13. What are the appropriate compliance strategies utilizing engineering controls, work practices, and respirators for reducing exposures to MC in particular workplace situations? Please state the extent to which the following control methods are protective and feasible for particular industries and employee activities:

a. Engineering controls such as ventilation, collection, isolation, containment, substitution of product or process, and modification of process or equipment; and

b. Work practices, housekeeping and administrative controls.

What is the lowest feasible exposure level that can be achieved for particular application groups by engineering controls and work practices alone? Are there any unique conditions in certain work settings where MC is produced or used where feasible engineering controls are not available?

14. Please provide information on engineering and work practice controls that would lower workers exposure to or below the proposed 25 ppm 8-hour TWA. Please include the cost and time necessary for their implementation.

15. OSHA's proposed rule for Methods of Compliance (54 FR 23991) does not require employers to institute all feasible engineering controls when only a negligible reduction in exposure is thereby achieved. Instead of using "negligible reduction" as the cut-off-point, should OSHA quantify the boundaries of exposure reduction and subsequent attainment level? If quantifiable boundaries of exposure reduction are included, how should they weigh consideration of health concerns (e.g., carcinogenesis) and safety hazards (e.g., phosgene production)?

16. Based on the description of production and process technology (Section V, below), OSHA believes that the engineering feasibility

determinations for the industrial facilities surveyed by OSHA are representative of the pertinent industries. Further, the rulemaking record indicates that it is technologically feasible to comply with the proposed PELs using engineering controls. OSHA is requesting public comment on these determinations. Are there particular circumstances where respirator use would be necessary to comply with the proposed PELs? Please explain any such circumstances and the frequency with which they would be expected to arise.

17. OSHA requests information regarding the number of workers exposed to MC, their current exposure levels, the methods of monitoring used to measure these exposures, the duration and frequency of exposure, the duties being performed, and the Standard Industrial Classification (SIC) Codes for industries and processes that utilize MC.

18. Are there specific activities which are generally known to cause exposure in excess of the proposed PELs? Should the standard include specific provisions prohibiting some or all such activities? Should the standard include provisions specifying controls that are known or proven to be effective in reducing workers' exposure?

19. As noted in Issue 11, there are some industries which have substituted away from use of MC. OSHA is seeking additional information on the feasibility of chemical substitutes for MC in industrial processes. What are the feasible chemical substitutes for MC and what are their limitations, if any? What are the differences in cost if these substitutes are used (including any necessary changes in equipment design, changes in product quality, or other costs incurred by substitution)? What are the impacts of substitution for MC with regard to safety (i.e., flammability, explosivity) and health (i.e., carcinogenicity, CNS effects) effects?

20. Has OSHA accurately estimated all costs associated with achieving compliance with the proposed new rule? Is compliance economically feasible for the affected industries? How would the time allowed to implement engineering controls and work practices affect these costs?

21. Is it appropriate to adjust the cost of compliance through giving credit for the sale of old equipment, savings on maintenance costs and time for repairs and decreased loss of product or shutdown time, when engineering controls are implemented?

22. In order to perform an economic feasibility analysis of the MC proposal, the Agency has developed a financial and economic profile of each industry

producing and using MC products. OSHA solicits information covering the last five (5) years to aid in the preparation of the economic feasibility analysis.

23. How does the proposed standard affect industry's economic position, particularly with regard to foreign import competition in the domestic U.S. Market, and the price of U.S. goods for export?

24. The MC record includes copies of the Preliminary Regulatory Impact Analysis and a report from OSHA's contractor, CONSAD, entitled "Economic Analysis of OSHA's Proposed Standards for Methylene Chloride", October 24, 1990 (Ex. 15a). Comments are requested on these analyses of the feasibility and the cost-effectiveness of the proposed standard and alternatives.

25. The Agency has prepared a draft Preliminary Regulatory Flexibility Analysis analyzing the impacts of the proposed standard on the small businesses which OSHA believes may be affected and has adapted the proposed standard to take into account the circumstances of small business where appropriate. Additional information is requested regarding:

a. What kinds of small businesses produce or use MC and how many of them would be affected by regulating exposures to MC?

b. Do any Federal rules duplicate, overlap or conflict with OSHA regulations concerning exposure to MC?

c. Will difficulties be encountered by small entities when attempting to comply with requirements of the proposed standard? Can any of the requirements be altered or simplified for the benefit of small entities while still achieving comparable protection for the health of employees of small entities?

d. What timetable would allow small entities sufficient time to comply?

26. OSHA has determined that employees in the shipyard industry are exposed to MC at levels which potentially exceed the proposed PELs.

a. Do the proposed requirements appropriately cover MC-related hazards to which shipyard employees are exposed?

b. Are there any MC exposure situations which are unique to shipyard employees?

c. What efforts have been made to control or prevent shipyard employee exposure to MC?

d. To what extent have employers controlled or protected employees from MC exposure such as through the use of engineering and work practice controls or respirators, respectively?



e. What has the implementation of any such measures cost? What has been the experience with those measures, in terms of effectiveness and reliability?

f. To what extent can shipyards reduce or eliminate the use of MC, through the use of mechanical methods of paint stripping or through substitution (see Issues 11 and 19)?

g. At its August 12, 1991 meeting, the SESAC discussed whether or not OSHA should allow employers whose employees use MC on fewer than 30 days a year to comply with the draft proposed PELs by any mix of engineering, work practices and respiratory protection. Some SESAC members noted that this threshold would allow small shipyards reasonable flexibility in determining how to comply with the PELs. OSHA solicits comments, supported by cost and benefit data, on the appropriateness of setting such a threshold for the shipyard industry or for other industries.

If OSHA were to set a threshold, at what point should it be set? Can a threshold be set that provides useful regulatory relief without unacceptably compromising employee protection? Are there sectors of the shipyard industry, or of other industries, for which the threshold approach would be particularly suitable?

27. OSHA has determined that many employees performing construction work have exposure to MC at levels which potentially exceed the exposure limits set by the proposed rule.

a. Do the proposed requirements appropriately cover MC-related hazards to which construction workers are exposed? Are there situations unique to the construction industry which indicate that any of the proposed provisions would be inappropriate for the construction industry? Are there additional provisions that should be included in the rule in order to provide adequate protection for construction employees?

b. Are there any MC exposure situations which are unique to the construction industry? What exposure levels have been experienced by construction workers?

c. What efforts have been made to control or prevent construction worker exposure to MC?

d. To what extent have employers controlled or protected employees from MC exposure, such as through the use of engineering and work practice controls or respirators, respectively?

e. What has the implementation of any such measures cost? What has been the experience with those measures, in terms of effectiveness and reliability?

f. To what extent can construction firms reduce or eliminate the use of MC in paint stripping through use of mechanical methods or substitution (see Issues 11 and 19)?

28. OSHA has determined that employees in agriculture may be exposed to MC at levels which potentially exceed the proposed PELs.

a. What processes or products in agriculture result in employee exposure to MC? What levels of exposures have been measured? What are the frequency and duration of such exposures?

b. Do the proposed requirements appropriately cover MC-related hazards to which agricultural employees are exposed?

c. Are there any MC exposure situations which are unique to agricultural employees?

d. What efforts have been made to control or prevent agricultural employees exposure to MC?

e. To what extent have employers controlled or protected employees from MC exposure such as through the use of engineering and work practice controls or respirators, respectively?

f. What has the implementation of any such measures cost? What has been the experience with those measures, in terms of effectiveness and reliability?

29. OSHA has provided for changes in the frequency of monitoring based on changes in the workplace or a demonstrated reduction in the exposure levels from above the PEL or STEL to below the PEL and STEL. The Agency is also considering adding a provision to the final rule which would explicitly increase the required frequency of monitoring from 6 months to 3 months, whenever a periodic monitoring sample was above the PEL or STEL. The frequency could again be reduced to 6 months upon collection of two samples at least 7 days apart which were below the PEL and STEL. Would this type of provision be necessary to give adequate guidance to employers as to when it is appropriate to increase monitoring frequency?

30. In the proposed regulatory text, the respirator selection table (Table 1) indicates the respirators that OSHA is proposing to allow in various ambient concentrations of MC. Filter-type respirators would not be allowed except in emergency escape situations. Does the respirator selection table in the proposed rule appropriately regulate the choice of respirators? What, if any, types of respirators should be prohibited from use by employees exposed to MC? What would be the basis for any such suggested ban?

As noted in the Summary and Explanation, NIOSH intends to further

study the breakthrough characteristics of MC in organic vapor cartridges and canisters in order to better assess the effectiveness of filter respirators for protecting employees from MC exposure. Is additional information available on the breakthrough times of organic vapor cartridges under various conditions? Have other sorbents been tested for their potential usefulness in MC filter respirators? Are there any circumstances under which filter respirators would provide adequate protection for employees exposed to MC? If so, please provide supporting data.

31. Should OSHA adopt the respiratory protection provisions contained in the proposed Methods of Compliance standard (54 FR 23991) instead of the provisions in the MC proposal? If so, are there any modifications that would need to be made in the provisions of that proposed standard in order to provide appropriate protection against exposures to MC?

32. Are there conditions, in addition to those proposed, under which respirator use should be permitted? OSHA has proposed to require fit testing for each employee who would wear a negative pressure respirator. Can employees who wear negative pressure respirators be adequately protected without quantitative fit testing? Do other fit testing protocols exist which would adequately assess respirator fit, in addition to the fit tests described in appendix C?

33. OSHA has proposed to require that each employee who must wear a respirator, but does not meet the 10-day minimum exposure requirement for inclusion in medical surveillance, be offered at least a cardiopulmonary examination to assess the employee's ability to wear a respirator. Is this appropriate? Should eligibility for the cardiopulmonary system evaluation be based on a certain minimum exposure period? If so, what should that exposure period be?

34. Are the medical tests specified in this proposed rule appropriate for facilitating early detection of the adverse health effects resulting from MC exposure? If not, please identify those tests regarded to be inappropriate and give the specific reasons. Are there other tests which should be required because they would be useful for diagnosing MC-related toxicity? For example, should OSHA require chest X-rays, urine analysis or liver function tests, notwithstanding indications that those tests are performed as "general" medical surveillance measures, rather than as means to detect MC effects?



Please include medical evidence to support your position.

35. Does the coverage of employees under medical surveillance include all employees whose exposures warrant coverage? If not, how should the coverage be expanded? If the present requirements for inclusion are retained, how much of the total MC-exposed workforce will be eligible to participate?

36. What additional provisions for medical surveillance should be included in the standard? What kind of clinical tests should be offered to employees exposed in emergency situations?

37. OSHA did not include a provision for Medical Removal Protection (MRP) in the proposed MC standard. Would MRP be beneficial for employees exposed to MC, due to the risk of material impairment to health? Do the health risks justify the inclusion of MRP provisions in the final rule? If OSHA decides to set MRP requirements for MC-exposed workers, what should these provisions be? Please provide information and data supporting your views.

38. OSHA is aware that many employees may be splashed with MC in the course of their occupational exposure. Therefore, the Agency is considering whether the proposed rule for MC should include requirements for quick-drench showers and eye-wash facilities to protect employees from the potentially serious health effects of MC splashes. Quick drench showers that could drench an employee with piped-in water applied with force, and eye-wash facilities that could flush the eyes repeatedly with a great amount of water, are already required in the OSHA health standard for formaldehyde (29 CFR 1910.1048(j)). In addition, the health standards for 1,2-dibromo-3-chloropropane (29 CFR 1910.1044(1)), acrylonitrile (29 CFR 1910.1045(m)) and ethylene oxide (29 CFR 1910.1047 (appendix A)) provide for wash and shower facilities to protect employees' eyes and skin from hazards.

OSHA seeks to determine if the eye and skin hazards of MC exposure necessitate promulgation of requirements for hygiene facilities to supplement those imposed through existing § 1910.141. In addition, the Agency seeks to determine if compliance with the hygiene facility requirements set out in one or another of the standards cited above would adequately protect employees. Accordingly, OSHA solicits comments regarding the following questions:

(a) What concentration of MC causes serious eye or skin effects? What are those effects? To what extent do they impair employee health and safety?

(b) Are there circumstances in which employees would contact liquid MC at concentrations that would cause serious eye or skin effects? What are those circumstances? Are there any additives commonly used in MC formulations which would add or detract from the skin and eye health effects? What are the effects of these additives?

(c) To what extent would compliance with existing or proposed requirements for personal protective equipment obviate a requirement for hygiene facilities?

(d) To what extent are MC-exposed employees already provided with hygiene facilities, such as quick-drench showers and eye-wash stations which would protect them from serious eye and skin effects? Do those systems provide adequate protection? How could that protection be improved? Which industries are most likely to have hygiene facilities in place? Which are least likely?

(e) What quick-drench shower or eye-wash systems are available for installation? What do they cost? To what extent do their features differ? How long from the time an order is placed does it take to get systems installed? How many employees are expected to share a single shower or eyewash facility? How close are those facilities to employee work stations? How close should they be?

(f) Are there industries where it would not be feasible to install quick-drench showers or eye-wash stations? Should OSHA limit the application of such a requirement to those employers who have a set minimum number of employees (such as 10)? Also, how necessary or feasible would such a requirement be for employees exposed to MC in the construction industry?

OSHA also requests information on any experience with eye or skin exposure, including the number of incidents, the severity of incidents, the number of lost work days resulting from those incidents, any measures taken to reduce eye and skin hazards and any measures taken to treat employees after eye or skin contact with MC.

39. As discussed in the Health Effects Section, OSHA is concerned that MC can be absorbed through the skin. What additional dermal absorption studies for MC are available? What is the extent of potential adverse health effects resulting either from dermal exposure alone or from a combined exposure by inhalation and dermal routes?

40. What types of personal protective equipment, such as protective clothing or barrier creams have been effective for protecting employees from exposure to MC in terms of decreased permeation

rates. What are the costs and availability of such products?

41. In order to underscore the importance of keeping hands and mouth free of contamination with MC, OSHA is considering adding a provision in the final rule to prohibit the following activities in regulated areas, eating, drinking, smoking, gum or tobacco chewing and applying cosmetics. Are these prohibitions reasonable and appropriate? Should any additional activities be prohibited in regulated areas?

42. What measurement and analytical methods are available for use in determining compliance with the MC proposed PEL of 25 ppm or the 12.5 ppm action level? Can these methods determine compliance with the proposed STEL of 125 ppm? How accurate are these methods? Are there any specific conditions for sample collection and preservation that should be included in the final standard so that reliable results can be obtained? In the proposed rule, requirements are set for the accuracy of analytical methods used in exposure monitoring. Are these requirements reasonable? Should OSHA consider more or less stringent requirements for these methods?

43. OSHA has evidence indicating inconsistency between data collected using sampling badges and those collected by adsorption on charcoal collection devices. OSHA solicits information on the conditions under which these sampling devices should or should not be used for measuring workplace exposures.

44. Should work places relying on objective data to document the fact that employees are not exposed at or above the action level be required to install alarm devices sensitive to concentrations at or below the action level? Are passive diffusion devices reliable enough to detect short-term low level exposure of employees to MC? Can they detect levels as low as 12.5 ppm?

45. Please provide any information available on potentially significant (negative or positive) environmental effects that may occur as a result of the proposal if implemented.

46. Substitution of other chemicals or processes for methylene chloride in certain industrial segments may impact the composition of waste streams generated by these facilities (impacting water quality and hazardous waste operations). OSHA is interested in obtaining information on how the chemical composition and volumes of these waste streams would change as the result of substitution for MC and whether the volume of waste requiring



special treatment or disposal as hazardous waste would change as the result of substitution?

47. The National Environmental Policy Act (NEPA), of 1969 (42 U.S.C. 4321 *et seq.*) requires that each Federal agency consider the environmental impact of major actions significantly affecting the quality of the human environment. Any person having information, data or comments pertaining to possible environmental impacts is invited to submit them with accompanying documentation to OSHA's docket. Such impacts might include:

a. Any positive or negative environmental effects that could result should a revised standard be adopted;

b. Beneficial or adverse outcomes between the human environment and productivity;

c. Any irreversible commitments of natural resources which could be involved should a standard be implemented; and

d. Estimates of the degree of reduction of MC and any other chlorinated hydrocarbons in the environment by the proposed OSHA standard and alternatives.

In particular, consideration should be given to the potential direct or indirect impacts of any action, MC substitute, or alternative actions on water, soil and air pollution, energy usage, solid waste disposal, or land use. Since there are reports of soil, air and water contamination by MC, what confounding effects does the continuous release of MC (e.g., at rates of 9 million pounds per year or more) have on the infant and New York State control populations in the Rochester, N.Y. plant epidemiological studies submitted to the record?

48. What other issues raised in the "Request for Information and Comments" for MC regulation (see *Federal Register* 51 (No. 228), pp. 42264 to 42266) should be further discussed prior to promulgation of a revised MC standard?

#### V. Chemical Identification, Production Technologies, and Industrial Uses

##### A. Chemical Identification

Methylene chloride (MC), also called dichloromethane (DCM), [chemical abstracts Service Registry Number 75-09-2] is a halogenated aliphatic hydrocarbon with a chemical formula of  $\text{CH}_2\text{Cl}_2$ , a molecular weight of 84.9, a boiling point of 39.8 °C (104 °F) at 760 mm Hg, a specific gravity of 1.3, a vapor density of 2.9 and a vapor pressure of 350 mm Hg at 20 °C (68 °F). Concentration of MC in saturated air at 25 °C reaches 550,000 ppm. MC has low

water solubility (1.3 gm per 100 gm of water at 20 °C), an extensive oil and fat solubility, and a low flammability potential. It is used as a flame suppressant in solvent mixtures (lower explosive limit of 12% and upper explosive limit of 19%). It is a colorless, volatile liquid with a chloroform-like odor and its odor threshold varies between 100 to 300 ppm. Contact with strong oxidizers, caustics and active metal powder may cause explosions and fires. Decomposition products during combustion or fire include phosgene, hydrogen chloride and carbon monoxide.

##### B. Production Technologies and Industrial Uses

###### 1. MC Production

MC is manufactured domestically in six plants owned by four companies. These companies are: Occidental Chemical in Belle, WV; Dow Chemical U.S.A. in Freeport TX, and in Plaquemine, LA; LCP Plastics, Inc. in Moundsville, WV; and Vulcan Materials Company in Geismar, LA and Wichita, KS. The approximate annual capacity of these six plants is 105, 150, 190, 80, 80, and 130 millions of pounds, respectively. The total annual capacity of the plants averages 735 million pounds a year (Ex. 15b). The actual production of MC, however, was estimated to be approximately 520 million pounds (234,000 metric tons) in 1987, down from an estimated 607 million pounds (275,000 metric tons) in 1984 (Ex. 7-220). The breakdown of the volumes of MC handled in 1988 for each industrial application group is shown in Table 1 (Ex. 15).

MC is produced commercially in the United States by two processes; (1) thermal chlorination of methane; and (2) hydrochlorination of methanol to produce methyl chloride followed by chlorination of the methyl chloride. In the first process, thermal chlorination of methane, methane and chlorine are fed to a reactor at moderate pressure and high temperature (340-370 °C).

TABLE 1.—ESTIMATED MC HANDLED

Application group	Estimated MC handled (millions of pounds)
Production.....	(467)
Polyurethane.....	54
Distribution/Formulation.....	250
Aerosols.....	106
Polycarbonate.....	7
Pharmaceuticals.....	28
Manufacture of Paints.....	28
Manufacture of Paint Removers.....	165
Paint Stripping.....	52

TABLE 1.—ESTIMATED MC HANDLED—Continued

Application group	Estimated MC handled (millions of pounds)
Degreasing.....	41
Cellulose Triacetate and Film Base Production.....	11
Electronics.....	40
Miscellaneous Usage (Food extraction, Pesticide formulation, and Ink).....	38
Solvent Recovery.....	37
	*497

\* Netting out rehandling; estimated total consumption equals 467 million pounds manufactured, minus 7 million pounds exported, plus 37 million pounds recovered from used solvent.

All four chlorinated methanes (methyl chloride, methylene chloride, chloroform and carbon tetrachloride) are produced by a chain reaction, with hydrogen chloride as a byproduct. The products of the reaction (including unreacted methane, HCl and  $\text{Cl}_2$ ) are separated by fractionation, scrubbing and drying operations. The relative yields of the different chlorinated methanes can be varied by recycling and control of the methane/chlorine feed ratio to optimize the yield of the desired products. MC may undergo secondary chlorination at ambient temperature during which chloroform and carbon tetrachloride are produced. Only one plant (Dow at Freeport, TX) is believed to produce MC by chlorination of methane. In the thermal chlorination process, for every mole of  $\text{Cl}_2$  introduced, a mole of HCl as a by-product is produced. Therefore, unless HCl is consumed locally in the production facility, its disposal may have environmental and economic impacts.

In the second and more widely used process, hydrogen chloride and methanol are reacted catalytically to produce methyl chloride. Methyl chloride is then reacted with chlorine in a process similar to that described above to produce MC. MC is separated from the other products of the reaction and purified by fractionation, scrubbing and drying operations. Stabilizers are usually added to prevent breakdown and inhibitors may be added to prevent corrosion.

MC production, by either method, is accomplished in an enclosed system and bypasses are considered to be an integral part of the continuous production process. As discussed in the control section, this continuous production process contributes significantly to the elimination or substantial reduction of worker



exposure to MC vapors. After production, MC is stored in outdoor tanks and is shipped in bulk quantity by rail car, tank truck, barge or in 55-gallon drums.

MC is the predominant solvent used for paint removal, metal degreasing, and in pharmaceutical and aerosol products. It is also used as a blowing agent in the production of polyurethane foams, in the cleaning of printed circuit boards, in the extrusion of triacetate fibers, and in a wide variety of other important industrial processes. The following are descriptions of these uses of MC.

## 2. Polyurethane Foam Blowing

There are currently an estimated 180 foam blowing establishments consuming 54 million pounds of MC with an estimated 1169 exposed workers. MC is used as a blowing agent and as a solvent for cleaning equipment in the production of polyurethane foam (PU). OSHA has no information on the quantity of MC used in foam blowing which is subsequently released into the air. However, the Agency has assumed that all of the MC consumed by these facilities is released into the air (Ex. 15).

In general, commercial PU products are complex plastics formed by the reaction of liquid isocyanate components with liquid polyol resin components. These components may also contain cell blowing agents, combustion retarding agents and catalysts. The finished products are polyurethanes or isocyanate plastics. PU products can be classified as rigid polyurethane foams, flexible polyurethane foams, and polyurethane elastoplastics.

The bulk of rigid polyurethane foam is made from polyether polyols, combustion-retarding agents, polymeric isocyanates, and low boiling halocarbon blowing agents. MC is not incorporated into the production mix, but is used only for filling and cleaning the mixing head.

Flexible foams are prepared from polyether polyols and TDI (toluene diisocyanate) and polymeric isocyanates. Carbon dioxide gas is the usual blowing agent. For very soft, low-density flexible foams, a small quantity of chlorofluorocarbon or chlorocarbon blowing agent may be added.

PU elastoplastics are made from either polyester or polyether polyols and diisocyanates. PU elastoplastics are available as pourable or injectable (Reaction Injection Molding) liquid systems, preformed pelletized solids, and sheetstock. These elastoplastics may contain combustion-retarding agents (Ex. 7-135).

*a. Use of rigid foam.* PU rigid foam is used in the refrigeration industry, in

construction and in plumbing as insulation material, for roofing and piping, and in refrigerated and air-conditioned containers and transportation tanks. Because of low thermal conductivity and good mechanical properties, rigid PU foam has several advantages over other insulation materials. These advantages include simplified production, reduced material usage, low weight, good weatherability and low water absorption. Another advantage is its ability to be sprayed to produce foam layers of any thickness on vertical or horizontal surfaces.

Rigid PU foam used as core material has important functions in the conventional assembly of various structures (e.g. bathrooms). The automotive industry uses foam for headliners and cavity foaming for interior liners of vehicles. Since 1970, rigid PU foam has been used in shipbuilding to make older barges unsinkable. The leaking barges are filled with rigid foam between the outer and inner walls at dry dock and thus made water tight. Certain types of PU foam have been introduced in specialized horticulture and in seeding nurseries. They are suited for vegetative reproduction (cuttings) in landscaping arrangements and as floral foam. Rigid PU is also used in surfboards and sailboats, weather protected VHF antennas and self-supporting cupolas of rigid PU foam ("radomes"). PU foam has good permeability to electromagnetic waves, good weather resistance and high strength to weight in high winds.

*b. Use of flexible foam.* PU flexible foam is useful for mattress and upholstery construction because of its properties of low weight, high air permeability, good heat and humidity transfer, durability, comfort and physiological compatibility. PU flexible foam has good "cushioning properties". That is, the ability to decrease shock-acceleration in relation to the surface load, make it particularly suitable for packaging sensitive goods. PU flexible foams are also used to optimize room acoustics over a wide frequency range because of their good sound absorption properties. Flexible foams are permeable to x-rays, and so are used for the support of body parts during x-ray examinations. Elastic bandages and bindings are further examples of uses of flexible PU foam for medical applications. PU flexible foam also has applications in sports and leisure activities, for example, as cushioning in gym, judo and wrestling mats, and as impact protection for high jumping and pole vaulting. Popular toys such as balls

and frisbees are also made from flexible PU foam.

*c. Use of PU elastomers.* The third major category of PU products is PU elastoplastics. The largest single application of high quality cast PU elastoplastics is the production of conveyor and roller systems. Because of high resistance to wear and tear, PU elastoplastics have a long life expectancy in rough conditions (i.e. in metal processing factories). Milling rolls made from PU elastomers are used in both the steel and paper industries where a high pressure load bearing capacity and/or high wear resistance are required. Naphthalene diisocyanate (NPI)/polyester-based cellular PU elastomers have peculiar and desirable dampening properties. Another large volume application for PU elastomers is in the construction of sports fields. PU elastomer systems are resistant to hydrolysis and rotting in all types of climates. PU elastomers are also used for pipe seals in underground construction, including formwork mats for relief concrete and wire and cable coatings in the electrical industry. Also, PU split leather has replaced leather in the shoe industry, because PU split leather has better abrasion resistance and less moisture uptake. In addition, torsion resistant ski boots and sports shoe soles are produced from polyelastomers.

*d. Production technology.* The following describes the production technology of polyurethane foam with the "one shot" process. This process is carried out without the use of solvent and is generally very fast, specifically in the presence of catalysts. Foam materials are prepared by simultaneously mixing the co-reactants directly with additives (blowing agents (e.g., MC), catalysts, foam stabilizers and flame retardants). The variability and the sequence of production processes and the type of equipment needed for each process affect worker exposure to MC.

Polyurethane foam ingredients, polyol and isocyanate, are delivered in drums containing approximately 250 liters. Two tanks per ingredient are installed. One tank contains materials which have to be conditioned before they are ready for processing. The other tank feeds the processing machine. The chemicals can be pumped from one tank to the other. The processor may alter the formulation by adding auxiliary agents such as blowing agents, catalysts, and pigment pastes to the main components. If direct metering is used, the additives are blended in line on the suction side of the pump with the use of premix chambers.



The formulation of the materials is accomplished apart from the metering equipment if machines with recirculation are used. At the blending stations, additives and auxiliary materials are metered with pumps and blended together by means of stirrers or static mixers. The mixture is then transferred to the machine tanks. Blending stations recharge the machine tank by pumping the materials against the tank pressure on demand from level switches, thereby achieving continuous production.

One of the most important processing parameters is temperature. Controlling the temperature is referred to as "conditioning" the materials in the tanks. Any change in temperature causes a change in viscosity, which in turn, influences the metering pumps. Adjusting viscosity and its associated temperament can be accomplished by changing the pressure in the machine tanks.

Metering pumps are necessary for processing flowable ingredients into reaction mixtures. Feed pumps are used to ensure proper and constant feeding of the metering pumps.

Different metering devices are needed, depending on whether high or low pressure machines are used, or whether the process is batch or continuous.

Since mixing is very important for polyurethane processing, the mixhead is commonly referred to as the heart of the machine. Within the mixhead is the mixing chamber, in which the components are brought together to form the reaction mix. The conditions for mixing must be constant during the process.

The reaction mix can be poured into open or closed molds. Pouring into open molds or onto a substrate can be done at one spot or along a pattern. Pouring into a closed mold is done through fill holes or gates. The diverter cone is one of the oldest devices for smoothing. The stream of the reaction mix coming from the mixing chamber is diverted to the wall of the outlet tube.

Although MC does not enter into the chemical reaction of PU production, MC is used as a blowing agent in the production of flexible PU and is used as a flushing media of the mixing head in the production of rigid foam. The cleaning of the mixing chamber and all the elements of the mixers with agitators is usually done by purging solvents. The small volumes of the impingement mixers allow purging with air. For example, in the process of mixing some of the reaction mixture is left behind in the mixing chamber after each pour. MC is used to flush the residual foam mix if

the duration between shots is longer than the cream time of the material.

The preferred agents for rigid polyurethane integral skin foams are low boiling halogen alkanes. Integral skin foams are formed from PU foam molding in such a way that parts consisting of a cellular core and a solid skin result. The skin is formed as an integral part and from the same material as the core foam. Although the standard blowing agent monofluoro-trichloromethane (R11), provides a satisfactory skin, 40% of this blowing agent can be replaced by MC to further improve the skin formation (Ex. 7-136).

*e. Substitutes for MC in foam blowing.* The substances that can be substituted for MC in foam blowing operations pose serious environmental problems.

Chlorofluorocarbon (Freon CFC 113), is currently used as an auxiliary blowing agent in some foam manufacturing facilities. The emissions of this chemical are considered to be a leading cause of the depletion of the earth's ozone layer. Freon is also more expensive than MC and requires storage in potentially dangerous pressurized vessels.

To date no chemicals or chemical formulations have been developed that clean foam equipment as effectively and safely as MC. Although other chlorinated solvents may be effective, they are more acutely toxic and more flammable than MC. Dimethyl formamide has been found effective for use as a dip tank solution in which the foam trough is soaked overnight. However, it is not practical for use where there is potential employee exposure due to its high toxicity (OSHA TWA is 10 ppm) (Ex. 10-4).

Trichlorofluoromethane (F11), dichlorodifluoromethane (F12) and 1,1,2-trichloro-1,2,2-trifluoroethane can also be substituted as blowing agents for MC. 1,1,2-Trichloro-1,2,2-trifluoroethane can be used instead of MC to produce rigid foam skin. Furthermore, 1,1,1-trichloroethane may function satisfactorily as a substitute when flushing the residual foam from the mixing chamber after the pour. However, none of these have been documented to effectively replace MC (Ex. 7-136) in large production facilities.

A new foam pouring technology has resulted in the development of foam formulations that do not require an auxiliary blowing agent, yet achieve the desired physical properties of the foam. This newly patented technology has not yet reached commercial production, and therefore, manufacturers currently rely on the pouring methods described above (Ex. 10-4).

### 3. Aerosols

There are an estimated 217 aerosol packing establishments consuming 106 million pounds of MC with an estimated 2,182 exposed workers. MC is used as a solvent, co-solvent, and vapor pressure suppressant in aerosol manufacture. MC aerosol use areas and subcategories are listed in Table 2. All of the MC used in the categories listed is released into the air during consumer use. Emissions during aerosol packing can result from: evaporation during product-solvent mixing operations; during aerosol can charging and MC transfer operations; volatilization of suspended droplets; and spills. The exact amount of MC released into the air from aerosol packing is not known (Ex. 15).

An aerosol is composed of the hardware (can; dip tube; valve spring; and button) and the contents (propellant, an active ingredient, and a solvent). A propellant is defined by the Department of Transportation as "a material which can expel the contents of an aerosol container at room temperature". The typical propellant is a liquified gas with a vapor pressure greater than atmospheric pressure (14.7 psia) that forces the contents of the can out when the valve is activated at room temperature (Ex. 7-133). MC cannot function alone as a propellant because of its low vapor pressure relative to other propellants (e.g. at room temperature, 25 °C: MC, 350 mm Hg; dichlorotetrafluoroethane, 1444 mm Hg) (Ex. 7-133).

TABLE 2.—AEROSOL USE AREAS AND SUBCATEGORIES

Use areas	Subcategories
Pesticides.....	Foggers; Direct Sprays; Residual Insecticides.
Paints and Finishes.	Spray Paints; Wood Stains; Varnishes; Finishes; Primers; Paint Removers/Strippers; Rust removers.
Automotive and Industrial Products.	Brake Cleaners; Carburetor and Choke Cleaners; Engine Cleaners.
Household Products.	Silicones; Spray Undercoatings; Mold Release Agents; other automotive and industrial products.
Other Products....	Artificial Snow; Glass Frosting; Electronic cleaners; Water Repellents; Paper; Carpet; Rubber Adhesives.

An active ingredient is a material essential for the specific application for which the aerosol was formulated (e.g., cleaning agent, insecticide, etc.). The active ingredients, solvents, and propellants are combined so that an



effective, attractive, and acceptable product is obtained (Ex. 7-133).

A solvent such as MC brings the active ingredient into solution with the propellants. Most propellants have poor solvent characteristics; in many cases, active ingredients are not soluble in propellants. In order to obtain a homogeneous mixture, it is necessary to add a liquid with the necessary solvent properties. It is sometimes desirable to have another liquid present which is not miscible with the propellant (e.g. water and propylene glycol). In these cases, a co-solvent such as MC or ethyl alcohol is added to obtain a homogeneous mixture. Another function of a solvent such as MC is to help produce a spray with a particle size that is most effective for a particular application. Solvents prevent the propellants from evaporating completely in air shortly after discharge from the can. Therefore, a solvent also assists in atomization and allows for a higher delivery rate (Ex. 7-133). MC is used as a solvent because of its high vapor pressure (350 mm Hg) when compared with other economically viable solvents, its high boiling point (39.8 °C), its compatibility with many types of formulations, and because it depresses the vapor pressure of high pressure propellants. As a result, the flammability of the mixture is reduced and the dispersion of the aerosol spray is enhanced (Ex. 15 B).

Depending on the volume of aerosol production, MC is shipped in tank cars, or in fifty-five (55) gallon drums. MC is either transferred directly from the shipping containers to the packaging line (to avoid loss of solvent due to volatilization), or it is transferred to storage tanks for mixing with other products (i.e. active ingredients and solvents). The aerosol can is charged with the active ingredients and solvent (either individually or premixed), and then filled with the propellant in an explosion proof room (Ex. 4-112). The valve and valve stem are added and the can is crimped shut. Cans are then placed in a hot water bath to test the integrity of the can at a specific temperature (temperature based on the percentage of MC and other components in the can). The cans are weighed to meet minimum requirements, checked for leaks, labeled, capped and packaged for shipment. Many companies contract out aerosol packing due to high plant costs. Some companies fill other companies' products as well as their own, while others only fill aerosols for other companies. Most production lines can be modified to accommodate different products. These modifications, however, can reduce the efficiency of a

plant (Ex. 15). Due to the various interrelated functions served by chlorinated solvents in aerosols or other packaging (e.g. paint formulation), there are no direct one-for-one substitutes. Modification of a formulation may require changes in the design of the container. There are many potential substitutes for MC in aerosols. Substitutes with diversified uses include 1,1,1-trichloroethane, tetrachloroethane, mineral spirits and water soluble formulas. Substitutes with limited uses include 1,1,2-trichloro- 1,2,2-trifluoroethane.

OSHA notes that some packagers have discontinued the use of MC because of health concerns or the development of solvents or co-solvents with equivalent or better properties than MC (Ex. 15).

#### 4. Polycarbonate Resin

OSHA has identified four polycarbonate resin manufacturers with an estimated 67 workers, producing a total of 710 million pounds of polycarbonate annually. MC is used as a solvent in the polycarbonate resin production. OSHA estimates that a total of 7 million pounds of MC are released to the air by polycarbonate resin manufacturers. These plants include the General Electric plant at Mt. Vernon, Indiana, the Bayer U.S.A. (Mobay Corporation) at Baytown, Texas, the Dow Chemical plant at Freeport, Texas and the Mobay plant at New Martinsville, West Virginia (Ex. 7-9, 7-141, 10-27).

Polycarbonate resin is an important engineering resin because of its unique properties (e.g. optical clarity and shatter proof properties). Polycarbonates are a special class of polyesters derived from the reaction of carbonic acid derivatives with aromatic, aliphatic, or mixed diols. They may be produced by the Schotten-Baumann reaction of phosgene with a diol in the presence of an appropriate hydrogen chloride acceptor (e.g. bisphenol-A with phosgene in the presence of an excess of pyridine), or by a melt transesterification reaction between the diol and a carbonate ester. That is, the phosgene first reacts with phenol to produce diphenyl carbonate, which in turn reacts with bisphenol-A to yield phenol in a molten solvent-free polymer. Transesterification is reported to be the least expensive route. That process was phased out, however, because there were many polycarbonate products which could not be produced using transesterification (Ex. 7-138).

Many medical devices are produced from polycarbonate (e.g., blood oxygenators used to purify blood and

intravenous harnesses). No good substitute is available for these applications. Polycarbonate can be sterilized both by autoclave and by gamma radiation.

Some other key applications for polycarbonate resin are in computers and business equipment, aircraft, small and large appliances, telephones, safety and sports helmets and optical discs. Polycarbonate sheets are used extensively in signs, windows and window protection, walkways, and roofing structures. Polycarbonate sheet is also used in greenhouses, solar and construction glazing, and skylights. Polycarbonates have also been used for energy recovery, both in the commercial and residential building industry (e.g., in active and passive solar energy collection applications). In the automobile industry, polycarbonates are used for weight reduction which impacts vehicle fuel economy. Safety equipment manufacturers have used polycarbonates for hardhats and safety glasses. Other items made from polycarbonates include the canopy for jet fighters, some missile parts and "bullet resistant glass" (Ex. 10-27).

Generally, the interfacial process is used in the production of polycarbonate resins. That is, during polymerization, a jacketed vessel equipped with an agitator is charged with the reactants and MC solvent. Phosgene gas is bubbled through the reactor contents. The reaction requires approximately 1-3 hours and is carried out at temperatures below 40°C (104°F). Pyridine and MC are recycled during the process (Ex. 8-11).

The polymerized-liquified reactor contents are then pumped to wash tanks for removal of residual pyridine using hydrochloric acid and water. MC is removed by steam stripping. The polycarbonate polymer is precipitated from the polymer-MC stream with an organic compound, such as an aliphatic hydrocarbon, and is separated by filtration. The filtered polymer is transferred to a dryer, while the solvent is recovered in a distillation column (Ex. 8-11).

Both General Electric and Bayer now use the interfacial process described above. In this process the bisphenol-A is dissolved as a disodium salt in aqueous caustic and reacted with phosgene bubbled into a methylene chloride layer. Reaction occurs at the solution's interface with the polymer "growing" into the methylene chloride layer. The polymer chain length is controlled by addition into the reaction mixture of a monohydroxyphenolic compound. The methylene chloride layer is then separated, and the polymer is isolated



by removal of solvent. At this stage, the various producers use a number of different processes, including devolatilization extrusion, granulation, and spray drying.

In devolatilization extrusion, a higher boiling solvent may be substituted for MC, concentrated, and run through a vacuum vented extruder to form pellets.

The granulation process introduces the methylene chloride solution into hot water. The solvent boils off and the friable polycarbonate resin is deposited. After drying, amorphous polycarbonate pellets are formed by extrusion of the granules.

Spray drying vaporizes the MC solvent with the concurrent precipitation of powdered polycarbonate resin. The powder is then extruded into pellets or other articles (Ex. 7-142). Most of the commercial polymer is produced and characterized in solution. Some is converted to film, whereas solutions are used to apply coatings to polycarbonate parts.

GE-PBG is the largest U.S. manufacturer of polycarbonate resin. At the GE bisphenol-A manufacturing plant, MC is a recrystallization solvent for bisphenol-A. Recrystallized bisphenol-A is dried and fed to the polycarbonate resin production process. MC is captured and recycled back for reuse, employing state-of-the-art engineering controls. Primary recovery means include low temperature condensation and carbon adsorption with regeneration. The overall MC recovery rate in this operation is 99.5%. GE is currently planning to change the bisphenol-A (BPA) production process to make the process a solventless one, by using a melting process to produce BPA instead of the MC recrystallization process (Ex. 7-216, 7-230).

At the GE Polycarbonate Resin Plant, MC is also used as a process solvent to carry polycarbonate polymer through the reaction and purification process. The polycarbonate resin is then isolated and the MC is recovered through a distillation process and recycled. Numerous process vents are combined and routed to vent absorbers. The overall MC recovery rate in this operation is 99.8%.

At the GE Polycarbonate-Polysiloxane Resin Plant (LR Resin), which is small compared to the Polycarbonate Resin Plant, MC is also used as a process solvent in the operation. At this operation, the overall MC recovery rate is approximately 93%.

As indicated above, the use of MC is a critical element in maintaining the product quality and safety specifications. Also, other solvents may crystallize, craze, crack, or mar the

surface of objects made from polycarbonates.

Pyridine, cresylic acid solvents, and p-dioxane are the nonhalogenated solvents which can be used as substitutes for MC. Hydrocarbons and aliphatic alcohols, esters, and ketones do not dissolve polycarbonates, and thus cannot be used as substitutes for MC in this application. Chlorobenzene, which may be used in the processing of polycarbonates, is an adequate high temperature solvent, but the polymer may crystallize and set to a hard gel state on cooling. Acetone promotes rapid crystallization of the normally amorphous polymer, and causes catastrophic failure of stressed polycarbonate parts. Aliphatic and aromatic hydrocarbons promote crazing of stressed molded samples (Ex. 7-138, 7-139, 7-140).

#### 5. Pharmaceuticals

An estimated 28 million pounds of MC are used in 76 pharmaceutical production facilities, exposing an estimated 1,007 workers. Most of the MC is used in pill coatings. MC is also used in the manufacturing of antibiotics, vitamins, contraceptives, and drugs used in the control of hypertension and diabetes (Ex. 10-8). It is estimated that 43% of the MC is released into the air during the production process and that 57% is recovered and processed for reuse (Ex. 7-9).

The pharmaceutical industry utilizes MC as an extraction solvent in the purification of pharmaceutical products and in pill coatings. Pharmaceuticals that are purified using MC as an extraction solvent include reserpine, cephalothin, cephaloride, cephradine, tolbutamide, and estrone. Those purification operations separate pharmaceutical products from by-products by solvent extraction either in a reactor or in a vertical column. MC is used because of its superior solvency and high volatility.

In the pharmaceutical industry MC is used in four successive stages of pharmaceutical production: Chemical reaction, product separation, purification, and drying.

In the chemical reaction stage, raw material solids and solvents other than MC, are mixed in a reactor vessel in which the chemical reaction is carried out, sometimes under elevated temperature and pressure. The stainless steel or glass-lined carbon steel reactor vessel is either an open tank or an enclosed vessel and is equipped with an agitator. Peripheral equipment such as condensers, a refrigeration unit, or a vacuum system can be added to allow the reaction to take place at very high or

low temperatures and/or pressures. Some reactors are equipped with a condenser for recirculation of the solvent.

After completion of the chemical reaction, the pharmaceutical products are separated during the product separation stage, the effluent is pumped from the reactor to a holding tank where the reaction products are washed to remove unreacted raw materials and by-products. The washed reaction products are then piped to various separation process tanks. Product separation often utilizes an extraction process in which a solvent preferentially dissolves one of the reaction products.

Distillation, crystallization and filtration are among the purification techniques used after product separation or extraction. Following product separation the crude extracted product is purified by crystallization of the desired compound from a supersaturated solution. A filter press is usually used to separate the concentrate from the solvent. The purified product and remaining solvent are then separated in a centrifuge. The cake may be further washed by water or another solvent to remove impurities before drying.

After the completion of purification processes, products are moved to dryers, such as tray, rotary or fluidized bed dryers which use hot air circulation or are operated under a vacuum to remove the remaining solvents or water from the centrifuged or finished product.

MC is released during storage, reaction, separation, purification, and drying processes. Storage emissions result from displacement of air containing the solvent during tank charging. Reactor emissions result from displacement of air containing MC during reactor charging, solvent evaporation during the reaction cycle, venting of uncondensed MC from the overhead condenser during refluxing, purging of vaporized MC following a solvent wash, and opening of reactors during the reaction cycle to take quality control samples. Distillation condensers can emit MC as uncondensed solvent. During crystallization, emissions can result from the venting of vaporized solvent if the crystallization is being done by solvent evaporation. If crystallization is accomplished by cooling of the solution, there is little emission. Dryers are potential large emission sources, emission rates vary during drying cycles, and with the type of dryer being used. Emissions from air dryers are normally greater than those from vacuum dryers mainly because air



dryers emissions are more dilute and difficult to control.

Among the possible substitutes considered (or tested) by some manufacturers were methanol and ethanol. However, these substances were rejected as substitutes, due to flammability and health concerns. Petroleum distillates are being used instead of MC by some facilities.

#### 6. Manufacturing of Paint and Paint Removers/Strippers

##### *a. Paint and coatings formulation.*

There are an estimated 390 paint formulation establishments with an estimated 1,808 exposed workers consuming 28 million pounds of MC. MC is used as a co-solvent in the formulation of paints and surface coatings, and as a co-solvent in aerosol spray paints. All MC in paints and surface coatings is released into the air (Ex. 15).

Paints and surface coatings can be classified into one of three categories based on their intended use. These categories are architectural coatings, product finishes for original equipment manufacturing, and special purpose coatings. Paint and surface coatings are formulated using binders, (a film-forming synthetic polymer or resin), a dispersion medium (i.e., a volatile solvent) and, in most cases, pigments and additives. Binders comprise the non-volatile portion of a coating's liquid component. They bind or cement a paint or coating to a surface. Synthetic resins, natural resins, and drying oils are the three types of binders used in paints and coatings. Synthetic resins represent over 90 percent of binder usage. Solvents, such as MC, are used to dissolve the binders so the paint or coating has a consistency suitable for application. Pigments are finely powdered insoluble solids dispersed in a liquid medium. These solids can significantly affect the properties of a coating system. Pigments may also be used for corrosion inhibition, reinforcement, and filler, as well as for color and opacity. Additives are used in paint formulation in relatively small quantities to facilitate manufacturing, and to improve package stability, application ease, and final appearance or performance. These additives rarely exceed 1 or 2 percent of the total formulation. They can be classified by function as paint driers, anti-skinning agents, mildew inhibitors, rheological modifiers, and latex paint additives. When paints or coatings are applied to a substrate, the dispersion medium evaporates under ambient or forced dry conditions and the remaining film-forming components coalesce to produce an adherent film. A wide

variety of solvents are used by paint formulators to achieve cost-performance objectives including:

- Aliphatic hydrocarbons (e.g., hexane, heptane);
- Aromatic hydrocarbons (e.g., acetone, methyl ethyl ketone);
- Alcohols (e.g., methanol, isopropanol);
- Ketones (e.g., acetone, methyl ethyl ketone);
- Esters (e.g., ethyl acetate, n-butyl acetate);
- Ethers (e.g., dioxane);
- Chlorinated hydrocarbons (e.g., MC, 1,1,1-trichloroethane); and water.

Of the chlorinated hydrocarbons, MC and 1,1,1-trichloroethane are the preferred chlorinated solvents because of their low flammability, fast evaporation rates, and high range of solvency (Ex. 15).

*b. Paint remover formulation.* There are an estimated 293 paint remover formulation establishments with an estimated 760 exposed workers, consuming 155 millions of pounds of MC. Organic paint stripping formulations are generally designed for optimum cost performance by careful consideration of the characteristic property of the organic paint film to be stripped, the sensitivity of the substrate that comes into contact with the stripping formulation, and the workplace and disposal environment in which the stripping is performed. There are four major end use applications areas for paint strippers. These are architectural, original equipment manufacturing and after market goods, government and military goods, and consumers. OSHA notes that the critical considerations in the selection of paint strippers are different for each of these application areas. A typical paint stripping formulation employs (Ex. 15):

*A primary solvent:* For fast penetration and swelling of paint film (e.g., methylene chloride);

*A co-solvent:* To increase penetration and solvency effectiveness (e.g., methanol, ethanol);

*An activator:* To attack film-substrate bond strengths (e.g., alkyl-arene-sulfonates, sodium lauryl sulfate);

*A thickener:* To provide thixotropy (i.e., the property of a liquid or gel that is characterized by the loss of viscosity under stress, and regaining of viscous state when stress is removed) if needed; (e.g., hydroxypropylmethylcellulose);

*An evaporation retardant:* To prevent evaporation before penetration (e.g., paraffin wax (mp 46-57 °C) at 1-3 wt percent);

*A corrosion inhibitor:* To protect the metal substrate from chemical attack (e.g., sodium benzoate).

Other additives may also be included, depending on the chemical nature of the film, the substrate, and stripping process cost performance requirements (Ex. 15).

MC is currently the primary solvent in the formulation of organic paint stripping agents. MC has the ability to penetrate, blister, and lift paint coatings. Organic paint stripping agents typically act by penetrating the cured paint film matrix, expanding interstitial structures to produce swelling of the film, dissolving uncured synthetic polymers and non-volatile formulation additives, creating physical stress on physical and chemical bonds at the film-substrate interface, lifting cured film from substrate, and entering between the lifted film and substrates to prevent re-bonding to the substrate (Ex. 15).

MC is shipped in tank trucks to paint stripper formulation sites across the nation. Formulated MC paint strippers are stored in drums or packaged in various size containers. Those drums and other containers are then shipped to industrial end points or to retail markets for consumer use (Ex. 15).

#### 7. Paint Stripping

MC has the unique ability to penetrate, blister, and lift paint coatings, therefore, it is the preferred paint remover (stripper). MC paint strippers are used in aircraft maintenance firms (large & small), furniture refinishing firms, and industrial firms.

An estimated 75 large aircraft stripping firms with an estimated 1,671 exposed workers consume 10 million pounds of MC. There are also 225 small aircraft stripping firms with approximately 799 exposed workers, which consume 3 million pounds of MC. The furniture stripping industry is estimated to have 4,000 establishments, with approximately 5,720 exposed workers consuming 14 million pounds of MC. In addition, there are an estimated 1,930 industrial firms with approximately 6,942 exposed workers, which consume 25 million pounds of MC (Ex. 15).

Most paint stripping operations purchase their stripper ready to use. However, some furniture refinishing operations make their own formulas. They purchase crude MC and mix it with other ingredients such as toluene, methyl ethyl ketone, and methanol. Although these formulations vary, the most effective ones contain between 70-90 percent MC (Ex. 7-132).

In aircraft maintenance (large and small), MC-based paint removers are often used to strip old paint from airplanes prior to repainting. The stripper is usually sprayed onto the



painted surface as a fine mist and allowed to blister the paint. The paint is then manually scraped off using nonmetallic scrapers and shoveled into drums. The application of stripper to hard to reach areas is generally accomplished manually using a brush or scraping tool which has been dipped into an open container of stripper. Finally, the airplane is washed with water or solvent rinse and brushed down to remove the remaining stripper and old paint (Ex. 15).

In commercial furniture refinishing operations, paint is stripped by either dipping the piece in an open tank containing the stripper (dip tank), spraying or brushing recycled stripper on the surface of the furniture in a large open tank (flow over system), combining use of a dip tank and a flow over system, or by manually applying MC with a brush. Stripping methods have not been standardized in this industry due to the diversity in size, construction, finish of items to be stripped, and the types of work areas and stripping solutions used. Typically, when a dip tank is used, a piece of furniture is manually placed in the dip tank and left until paint blisters. If a piece is not completely submerged it may be manually rotated to allow complete coverage. The piece is then removed to another area to be manually scraped. This process is repeated until the surface is clean of paint. Hard to reach areas are hand brushed with MC stripper. The furniture is then washed down with water and allowed to air dry.

When the flow over system is used, the furniture is placed in a large open tank which connects to a small reservoir of stripping solution. The solution is then pumped through a brush onto the surface of the furniture and allowed to blister the paint. The portion of the solution that does not adhere to the furniture is recycled through the system and back into the reservoir. Then, the blistered paint is scraped off. The furniture is then washed down and allowed to dry. Paint chips and paint sludge are manually collected in drums or trash cans and disposed of as normal refuse. The spent stripping solution is either recycled, disposed of as hazardous waste, stored on site or left to evaporate. Because of economic considerations, MC is not usually recovered from spent solution (Ex. 7-132).

Industrial use includes removal of paint from paint conveyor hooks and trolleys, reworking of defective paint and coatings, and cleaning of paint booths. This is done by dipping and spraying of parts, removal of blistered

paint, and washing down to remove excess solvents (Ex. 15).

Some alternatives to MC used in the furniture refinishing industries include petroleum distillates, acetone, mineral spirits, alkali, and water soluble formulas (Ex. 15).

An alternative to MC paint stripping that is being tested in the stripping of aircraft is plastic media blasting. This process blasts small plastic beads, usually 30 to 40 mesh in size, with rough edges onto the painted surface. This process is less labor intensive, (generally ten times faster than the MC stripping process), and generates less waste for disposal, so it has some cost advantages over MC paint stripping. While bead blasting may save time, special efforts are necessary to protect certain components of an aircraft such as plastic windows, surfaces that are protected with soft cadmium coatings, and radomes that are painted with rain-erosion coatings. The biggest disadvantage is that beads abrade the aircraft metal surface, potentially causing damage and reducing the life of the plane. Chemical strippers can, however, corrode aircraft surfaces, and deteriorate concrete floors as well. Plastic media blasting can also raise enormous metallic and paint dust clouds if proper blasting and control equipment are not used and correct procedures are not followed. Some other potential problems with abrasive blasting which limits their use are (1) personnel resistance to change; (2) trapped media in aircraft; (3) physical handling of blast nozzle, workstand, etc.; (4) seam seal on dynamic components (Ex. 8-22).

#### 8. Degreasing and Metal Cleaning

OSHA estimates that there are 90,293 exposed workers in 22,652 establishments using 23,664 cold degreasers consuming 31 million pounds of MC; approximately 271 exposed workers in 124 establishments using 129 open top degreasers consuming 7 million pounds of MC; and approximately 177 exposed workers in 107 establishments using 111 conveyerized vapor degreasers consuming 3 million pounds of MC. Out of the 41 million pounds of MC used in degreasing, it is estimated that 37 million pounds are reclaimed (recovered) in 40 reclamation plants throughout the U.S. (Ex. 15).

MC is used as a degreasing solvent to remove drawing compounds, cutting fluids, coolants, and lubricants from metal parts. It can be used in cold cleaning, open top vapor degreasing, or conveyerized vapor degreasing. It is difficult to characterize the establishments that use MC for metal cleaning or degreasing because of

widespread and nonspecific use patterns. MC is generally chosen when other organic solvents fail to provide the desired characteristics such as non-flammability, non-reactivity with metals, the ability to dissolve a broad range of greases and industrial chemicals, high solvency for most industrial contaminants, and a rapid rate of evaporation (Ex. 4-41). The three methods of metal degreasing are described, as follows.

(i) *Cold degreasing*.—Most cold degreasers are open top stainless steel tanks. The cleaning operations used in cold degreasing include spraying, flushing, brushing and immersion in the solvent. Typically, dirty parts are sprayed with MC and then soaked in the degreasing tank. When cleaning is completed, the parts are usually suspended over the tank to drain or are placed on a rack outside the tank with the solvent drippings directed back into the tank or otherwise collected for subsequent reclamation. Some degreasers are equipped with agitators that operate while the parts are immersed in the solvent. This enhances the cleaning efficiency of the solvent (Ex. 15).

MC is also applied with a rag to provide a soft abrasive cleaning action. This activity is categorized as "cold cleaning" (Ex. 15).

(ii) *Vapor degreasing*.—Open top vapor degreasers operate by condensing hot solvent vapor on colder metal parts. The typical open top vapor degreaser consists of two sections: a lower section with a reservoir containing liquid solvent and a heat source which boils the solvent to create a vapor, and an upper section containing only the vapor and emission control systems. Metal parts soiled with grease, oil, metal particles, etc., are lowered, usually in a basket, into the solvent vapor zone of the tank with the aid of a manually-operated or automatic crane. The hot vapor condenses on the cooler metal parts and the condensate dissolves the soil, carrying it along as it drains back into the boiling liquid reservoir below. When the metal parts reach the vapor temperature, the condensation stops. The vapor degreasing process takes advantage of the fact that the solvent boils at a much lower temperature than the oil and grease. If the temperature of the liquid reservoir is maintained at the boiling point of the solvent, only pure solvent vapor is found in the vapor zone of the degreaser. As water can interfere with the degreasing activity, degreasers are also equipped with a water drain off valve. The cleaning efficiency of this process can be increased by spraying



immersed parts with solvent or by dipping them into the hot MC liquid.

(iii) *Conveyorized degreasing.*—These are operated with either cold or vaporized solvents. Parts are placed on a conveyor which carries them into the liquid solvent or through the vapor zone and out the other end for drying and or subsequent handling. Conveyorized degreasers are generally continuously loaded and are almost always hooded or enclosed.

Use of the vapor degreasing process has increased in recent years due to improved equipment design. However, MC cannot be used in vapor degreasing of parts soiled with grease or oil that has a high paraffinic content because a high rate of solvent flushing is required in such circumstances. Furthermore, MC cannot be used on thin parts because they heat too quickly and good condensation cannot be achieved (Ex. 4-041).

Degreasing equipment must be cleaned periodically to maintain its efficiency. High exposure to MC is possible when tanks are being cleaned because the worker often simply empties the tank of solvent, rinses it with water from a high pressure hose and then climbs inside the tank to scrub it with brushes (Ex. 7-132).

Many solvents are being used besides MC for degreasing. Examples are 1,1,1-trichloroethane, mineral spirits, and perchloroethylene. In addition, a wide variety of petroleum distillate products such as gasoline, kerosene, and turpentine are used (Ex. 15). The feasibility of using these substitutes depends on the characteristics of the parts to be cleaned and the level of cleaning desired. Since the same tanks or equipment are used for multiple tasks, emptying the tanks containing the substitute whenever a higher level of cleaning is required, may render the use of substitutes impractical in some facilities.

#### 9. Cellulose Triacetate Fiber and Cellulose Triacetate Photographic Film Production

*a. Cellulose triacetate.* MC is used by one company, Celanese Corp., at Cumberland, Md., as a solvent for spinning cellulose triacetate fibers. It is estimated that all of the approximately 4.5 million pounds of MC used at this facility are released to the air (Ex. 7-9).

The first cellulose fiber manufactured was cellulose triacetate (CTA). However, CTA was not soluble in solvents that were then available and safe to use. Because of this, CTA was never produced on a large scale in the early days of rayon and the process did

not reach the commercial production scale for many years.

In later years, this situation changed. The manufacture of cellulose triacetate now proceeds on a large scale: Tricel (British Celanese Ltd.) is made in Great Britain. Arnel is made by the Celanese Corporation of America. Trilan is produced by Canadian Celanese Ltd. The two main reasons for the development of these fibers are:

(i) The availability of solvents such as formic acid, glacial acetic acid, dioxan and cresol that are easy to use, safer than chloroform to handle, inexpensive and available in large quantities. MC, which is also an excellent and inexpensive solvent for the production of secondary acetate, has been used for triacetate production since 1930.

(ii) The development of the synthetic fibers such as Nylon, Orlon and Terylene has demonstrated that there are many applications for hydrophobic fibers for which the hydrophilic viscose and (secondary) cellulose acetate rayons and natural fibers are not satisfactory substitutes.

The raw material for the manufacture of cellulose triacetate, is either purified cotton linters or specially pure grades of wood pulp. In either case, the cellulose is pretreated with acetic acid (acetylation). There are two methods of acetylation used in the treatment of cellulose triacetate. In the first method, the activated cellulose is esterified with acetic anhydride and acetic acid, using sulfuric acid, as a catalyst. When acetylation is complete, all of the cellulose fiber will have passed into solution. The cellulose triacetate is then precipitated into water, washed and dried in percentage of spinning. The dry-spun cellulose triacetate fiber is passed over a wick containing an anti-static agent and is collected on cap-spinning bobbins if it is in the continuous filament form. If required for staple, a number of ends are collected into a tow as they leave the spinneret, no twist is inserted, and the tow is crimped and cut to the desired length.

MC is a good solvent for dry spinning the fiber. Ordinary secondary fiber can be processed using acetone as a solvent, since acetone (80% acetone/20% water) dissolves ordinary secondary fiber whereas MC only swells this fiber. Conversely, MC (80% MC/20% water) dissolves cellulose triacetate but only swells secondary acetate. This property also makes MC useful for distinguishing secondary acetate from triacetate fibers.

Some of the advantages of CTA fibers are described here. Cellulose triacetate is resistant to boiling water. In addition, it can be heat-set like synthetic fabrics so that it will hold pleats that have been

deliberately inserted even if subsequently washed (without shrinking like Nylon and Terylene) and so that it will resist subsequent creasing. Also, the chemical resistance of triacetate is generally superior to that of secondary acetate, and it has biological resistance (defenses against bacterial, fungal and insect attack). It is a bright fiber and can be subdued by the incorporation of titanium dioxide. In addition, it has very high electrical resistance, which is only exceeded among textile materials by Terylene, Polyolefins, Teflon and glass.

Nearly all of the cellulose triacetate is used for ladies' apparel. Much of it is used to make 100 percent continuous-filament open fabric. High bulk Tricel is used in knitwear.

The solvents which can substitute for MC in the manufacture of cellulose triacetate are: Chloroform, formic acid, glacial acetic acid, dioxan (slowly) and cresol (slowly). Triacetate is swollen by acetone (also partly dissolved), ethylene dichloride and trichloroethylene.

In the second method of acetylation that involves the use of a non-solvent process, the activated cellulose is esterified with acetic anhydride in the presence of a non-solvent such as benzene, which preferably has a slight swelling action on the esterified cellulose. An acid catalyst such as sulfuric acid, toluene sulfonic acid, or perchloric acid is used. The acid catalyst is then removed from the fiber using a heated non-solvent medium with acetic acid. The purified solid cellulose triacetate is then dried.

Also, the wet spinning process can be used instead of the dry spinning process to produce cellulose triacetate. In this process, which does not involve the use of MC, cellulose triacetate is dissolved in glacial acetic acid and extruded into either water or dilute acetic acid. Arnel 60 was wet-spun, and it was considerably stronger than ordinary dry-spun Arnel. But it has been discontinued, and probably all of today's triacetate fiber is dry-spun (Ex. 7-137).

*b. Flexible photographic film base manufacturing.* MC is used in the film industry for casting of cellulose triacetate film base and light sensitive emulsions as well as for film splicing. Typical cellulose casting products using MC are films for still cameras, motion pictures, micrographic, and graphic arts.

The principal application of MC in this industry is as a process solvent in the casting of cellulose triacetate, which is used as the base for photographic film (Ex. 15). The manufacture of cellulose triacetate film starts with the pouring of a film substance on a metal drum or a



continuous metal belt. After evaporation, a film having a thickness of .02 to .03 mm forms. The film is then passed through a water sealer by means of a heated cylinder onto a chromium roller where it is dried. For safety reasons, the drum and metal belt are in a hermetically sealed channel separated from the water sealed environment and closed off by a moderately high nitrogen pressure. The cellulose triacetate is in solution in an organic solvent, of which 65% is MC. Other components of the solvent are methanol, dibutylphthalate, and triphenylphosphate (Ex. 7-26).

Exposures can occur during the evaporation of the MC into the air during manufacturing, set up of materials, disruption in apparatus, and when pouring the film onto the metal drums (Ex. 7-26).

In film splicing, MC is used as a solvent in the glue used to splice pieces of film together. The MC dissolves the plastic interfaces of the pieces and then evaporates, leaving the pieces "welded" together. This process is either done manually or by machine (Ex. 15).

#### 10. Electronics

There are an estimated 1,059 electronics establishments consuming 40 million pounds of MC with an estimated 4,720 exposed workers. MC is used in the electronics industry primarily as a photoresist stripper. Resist strippers are used in the production of integrated circuits and printed circuit boards. MC is also used in this sector as a vapor degreaser to remove the flux from the printed circuit boards after soldering (Ex. 8-28). Based on available documentation, OSHA believes that all of the MC used by the electronic production facilities is released into the air, rather than recovered.

MC is also used in the manufacture of semi-conductors to degrease semiconductor wafers, before, during and after fabrication of the integrated circuits on them. In addition, MC is used in the diffusion process to introduce dopant impurities which modify the electrical properties of a semiconductor (Ex. 15).

Printed circuit boards are plastic sheets on which conductive paths are formed in a specific pattern for the purpose of interconnecting electronic components such as semiconductor devices, resistors, and capacitors. Printed circuit boards can be one-sided, double-sided, or multi-layer. In general, laminated printed circuit boards are processed into electronic circuits by the following steps:

(i) Application of a polymer-based photosensitive resist over the entire board surface;

(ii) Masking of the resist with the appropriate circuit design;

(iii) Photoexposure of the resist;

(iv) Development and removal of either exposed or unexposed soluble photoresist depending on whether the resist is positive or negative, respectively;

(v) Etching to remove the exposed copper; and

(vi) Stripping (removal) of the remaining resist (Ex. 4-41).

Potential solvent substitutes for MC for this application include: 1,1,1-trichloroethane, chlorofluorocarbons (CFCs), acetone, alkali (caustic) and Yzio Dip. However, some firms reject these substitutes because of a lack of effectiveness and reactivity of metal with the solvents. The chemicals OSHA found most often mentioned as having been considered (or tested) and rejected as substitutes were 1,1,1-trichloroethane, acetone and alkali (caustic), except for its use in flux removal (Ex. 15).

OSHA notes that aqueous cleaning is an alternative to the use of MC (vapor degreasing) for the removal of flux from printed circuit boards. This method involves the use of water under pressure to clean boards, provided that the flux used (before the soldering of boards) is water soluble. Sometimes a detergent is added to the water when the wet soldering process is used. Aqueous cleaning has proven to be an effective method for the removal of flux from printed circuit boards (Ex. 7-134).

The best alternatives for many electronics uses are blends that substitute CFCs for methylene chloride. Because of the issue of ozone protection in the stratosphere, international treaties have been signed to limit the production of CFCs. OSHA has assumed, therefore, that no CFC substitution will take place due to this proposed regulation.

#### 11. Miscellaneous Uses

a. *Food extraction.* MC is used to extract desirable constituents and mixtures of constituents from solid food raw materials, intermediate products and by-products (Ex. 4-32). The three major applications of MC that have been identified in food processing are the decaffeination of coffee, the extraction of hops, and the manufacturing of oleoresin. OSHA estimates that these operations consume over 10 million pounds of MC each year.

The two companies previously known to use MC for decaffeination were General Foods and Tetley. General Foods has indicated that they have phased out the use of MC. Tetley, in turn, indicates that MC decaffeination accounts for only a small portion of the

estimated consumption. For all practical purposes, MC is no longer used in decaffeination by either of the companies (Ex. 15).

Only one manufacture, Hopstrack Inc. uses MC to extract hops. It is estimated that less than 40,000 pounds are used for this purpose. Also, it is estimated that approximately 30,000 pounds of MC are being used in the manufacture of oleoresin spices (Ex. 15).

MC is also used to extract gossypol from cottonseed products, nitrite from various crops, lecithin, phosphatide, cephalin and digalactosyl diglycerides from potatoes, the aroma-containing fractions from cocoa and antioxidants from glucose-ammonia browning reaction products (Ex. 4-32).

Heterogeneous solid-liquid extraction was used in some decaffeination processes. In most cases, an occluded aqueous solution is produced by steaming green coffee beans. This solution contains both dissolved non-caffeine coffee solids and caffeine, and becomes progressively leaner in caffeine as extraction proceeds. MC or supercritical CO<sub>2</sub> are used as solvents in the external solution, the extract. The extract becomes progressively richer in caffeine as the extraction proceeds, but, if things are arranged properly, it should contain scarcely any non-caffeine solutes.

The solids involved in most food extraction processes consist of a matrix of insoluble solids, the "marc" and occluded solution. It may also contain undissolved solute and a nonextractable secondary phase (e.g. coffee oil in water-soaked coffee grounds). This secondary phase can be treated as part of the marc. In decaffeination, the coffee oil which is naturally present in green coffee beans significantly affects the amount of the solvent absorbed by the beans.

The overall extraction process can be controlled and the absorption of solvent by green coffee beans can be minimized by using a combination of solid-liquid and liquid-liquid extraction. A green-coffee solution which contains almost no caffeine, is used to extract caffeine from green coffee beans in a diffusion battery. The caffeine is then extracted from the green-coffee solution by using a solvent such as MC. Steam is then used to thoroughly strip MC from the green-coffee solution. The solution of caffeine in MC is treated so as to recover caffeine and caffeine free MC, which is reused in the extraction process. The green coffee beans are then washed to remove extract which clings, steamed to remove any MC which has been indirectly absorbed, dried and roasted.



The produced roasted coffee contains no more than 3% and usually less than 1.5% caffeine. Steaming, drying and roasting are also necessary when heterogeneous solid-liquid extraction is used, but steaming must be carried out for a much longer period (Ex. 4-32).

Benzene was used in the early 1900's to extract caffeine from coffee and still is used in certain hop extraction sequences. Supercritical, dense CO<sub>2</sub> gas is now used commercially to extract caffeine from coffee and to extract bitter flavoring agents (humulones and isohumulones) from hops. Solutions of CO<sub>2</sub> in acetone have also been used in coffee extraction and solutions of CO<sub>2</sub> in acetone and butane have been used for extracting hops (Ex. 4-32).

*b. Ink use.* MC is used in the formulation of ink and ink solvents. It is estimated that there are 37 ink solvent manufacturers, with approximately 143 exposed employees, which consume 9 million pounds of MC, and 10,482 ink solvent users, printing and newspaper firms, with approximately 34,868 exposed employees which use 9 million pounds of MC. Printing and newspaper firms use an ink solvent formulation called "blanket wash" to clean printing plates and equipment.

Many different ink and solvent formulas are necessary for printing, because the paper and other materials used in printing have different textures. Printing inks are compounded from pigments or solid ingredients which supply the body and color; the fluid ingredient or vehicle which carries, distributes, and binds the pigments to the surface; and various waxes and other compounds.

Finished inks are packed in metal cans, in metal or plastic pails or in metal or fiber drums, and occasionally, in tote bins. High volumes of fluid ink (e.g. news, flexo or gravure) are usually delivered in tank cars.

The main processes, cited by ink and ink solvent formulators, where exposures occur, were the actual formulation of the products and the filling of cans and drums.

Petroleum distillates, Agatane, mineral spirits, and the use of water soluble formulas have been considered as potential substitutes for MC (Ex. 4-32).

*c. Pesticide manufacturing.* In the formulation of pesticide products, MC is sometimes used as a solvent in order to produce liquid products from granular active ingredients. There are an estimated 60 manufacturers with 120 exposed employees who use 10 million pounds of MC.

Products which have been substituted for MC include petroleum distillates

(most often used), aqueous formulas, perchloroethylene, carbon tetrachloride, mineral spirits, and Agatane. Substitution is unlikely in most of the industry because the processes are engineered for a particular chemical and replacing the current solvent would require significant modifications to equipment designs and operational functions.

*d. Solvent recovery.* Reclamation is the process of restoring a waste solvent to a condition that permits its reuse. There are an estimated 40 recovery facilities employing approximately 161 workers, which collect an estimated 37 million pounds from degreasing and pharmaceutical firms. The MC that is used in paint removers is not usually recoverable (Ex. 10-8). OSHA notes that MC may be recovered in other industries as in electronics. OSHA believes, however, that such additional recovery operations handle little MC.

Solvents are stored both before and after reclamation in containers ranging in sizes from 55 gallon drums to 2000 gallon tanks. Once waste solvent is received it can either be piped or loaded manually into recovery process equipment.

There are three major steps in solvent recovery: Initial treatment, distillation, and purification. The initial treatment consists of vapor recovery and/or mechanical recovery. The former includes condensation, adsorption, and absorption while the latter includes decanting, filtering, draining, settling, and centrifuging. The solvent recovered from the initial treatment is passed through the distillation process to remove dissolved impurities. The final purification process removes water by decanting (mechanically separating water and solvent layers), or by salting (passing the solvent through a calcium chloride bed where the water is removed by adsorption). Special additives are added to the solvent during the purification process in order to renew the solvent. Any waste materials left after the solvent has been reclaimed are disposed of by either incineration, land filling, or by deep well injection. Points of possible emissions include storage areas, tank vents, containers, and incinerator stacks (Ex. 15). The MC recovery industry is expected to continue as long as waste that contains recoverable MC is available.

*e. Other uses.* OSHA is aware that MC is used in the construction and shipyard industries. OSHA's contractor, CONSAD Research Corporation, has collected preliminary use and exposure information concerning these industries. Discussion of this data can be found in

the "Summary of Preliminary Regulatory Impact and Regulatory Flexibility Analysis", below. MC is also used in cleaning petroleum or asphalt barges and in the textile industry as a dye carrier solvent. Another use of MC is as a solvent, primarily for cleaning up tools and resin spills, in the manufacturing of fiberglass products such as boats, tub enclosures, and automotive parts (Ex. 15).

## VI. Technological Feasibility Assessment of Engineering Controls To Reduce Employees' Exposures

The technological feasibility of engineering controls for the reduction of workers' exposure depends mainly on the physical and chemical characteristics of the toxic substance to be controlled, and its associated production or process technologies.

In the assessment of the technological feasibility of engineering controls, OSHA used available published information as well as information gained from OSHA's site visits. Methylene Chloride, CH<sub>2</sub>Cl<sub>2</sub>, MC, the substance to be controlled, is a colorless liquid with a chloroform-like odor. The MC odor threshold varies from 25 to 300 ppm. MC has a boiling point of 39.8 °C (104 °F) and a high vapor pressure at work room temperatures. At 20 °C (68 °F) and 25 °C (77 °F) the vapor pressures are 350 and 440 mm Hg, respectively. MC is corrosive to some surfaces. The physical contact of MC with strong oxidizers, caustics and active metal powder may cause explosions and fires. Decomposition products during combustion or fire include toxic by-products such as phosgene, hydrogen chloride and carbon monoxide (partial oxidation).

This document includes a separate section for each industrial sector involved in the production or the use of MC. Each section addresses the technological feasibility of achieving the proposed PELs.

As indicated before, in determining the technological feasibility of engineering controls, the combined physical and chemical characteristics of MC are considered. Based on the record developed to date, OSHA has tentatively concluded that the engineering and work practice controls needed to achieve a 25 ppm PEL and a 125 ppm STEL are technologically feasible.

The assessment of the feasibility of engineering controls relied primarily on CONSAD's (OSHA's contractor) evaluation and analysis, where it was demonstrated that the use of local exhaust ventilation (LEV) and other



similar controls are capable of achieving the PELs in most establishments. In addition, OSHA's independent evaluation of the data collected during several site visits to the various MC facilities, has proven to be consistent with CONSAD's conclusion, and has supported its technological feasibility determination for achieving the PELs. CONSAD's conclusion and OSHA's independent findings of the technological feasibility collectively indicated that the measures available to abate employee exposure include: the use of local ventilation systems (to remove the MC vapors emitted from localized or point sources); the use of general dilution ventilation (to reduce MC concentrations resulting from diffused or fugitive sources); the use of magnetic pumps and floating gauges (to eliminate or significantly reduce the leakage from process lines); the use of submerged lances equipped with double concentric jackets (to remove MC vapors during drum filling); the use of in-line quality control sampling techniques, connected directly to analytical equipment (to eliminate manual sampling and its associated workers' exposure); and the use of chilling coils (to reduce the MC temperature and its associated rate of vapor release).

The majority of the above control devices are currently available in virtually leak-proof construction/design (e.g. magnetic pumps) or corrosion resistant design (stainless steel chilling coils using water/glycol cooling media). These improved designs render control equipment to require little or no maintenance during their normal useful lives and under normal operating conditions. OSHA further determined that proper design and implementation of control systems, including consideration of the temperature of MC, size and capacity of process equipment, and volume of MC projected to become airborne (released), are critical to the successful operation/function of controls and reduction of workers' exposure.

Other measures that can be successfully implemented to lower exposure levels include providing enclosures equipped with activated charcoal beds or similar air cleaning media for operators of mobile equipment; installing fresh air supply islands for fixed workers' stations, supplying down-draft ventilation, whenever workers can be stationed on exhausted grated platforms (e.g. workers in paint stripping whose duties require very limited mobility), and improving the efficiency of vapor recovery systems by increasing the capacity of the heat

exchanger to lower the temperature of the cooling media.

OSHA believes that some of the above described control systems may have broader application and could result in higher operating efficiency than LEV systems. Insofar as employers can implement control systems that surpass LEV systems in effectiveness, the Agency anticipates that the need to comply with ancillary provisions, such as those covering regulated areas and medical surveillance, could be eliminated or significantly reduced. Therefore, OSHA requests public comments on this issue. The final standard will reflect the information received in response to this request.

OSHA assessed the technological feasibility of the engineering and work practice controls that are needed to comply with the proposed PELs, without regard to extensive use of respiratory protective equipment. OSHA contemplated the use of respirators, only where the implementation of all feasible engineering and work practice controls would not enable employers to comply with the proposed PELs. The technological feasibility and utility of each of the control technologies is discussed in detail below for each of the industrial segments expected to be impacted by the proposed standard.

#### A. MC Production

Methylene chloride is produced in an enclosed system using continuous processes, as described in section IV. Production equipment (tanks, condensation towers, drying towers, pumps, valves, conduits and piping, etc.) is opened only for maintenance and very seldom for sampling quality control specimens.

Most components of production equipment, including storage tanks and loading facilities, are located outdoors. Therefore, leaks from gaskets, pipe couplings, pumps, valves, in-line sampling ports, etc. are diluted and dispersed into the atmosphere. Consequently, exposure of workers to MC is minimized (Ex. 7-209).

In addition, because of the automation of this production process, workers spend very little time in the field (in the vicinity of production equipment) and the majority of their time is spent in the control room, where no exposure to MC exists.

Sources of workers' exposure in the production facilities of MC are limited to leaks from process equipment (pipes, valves, tanks, towers, and pumps), disassembling process equipment and disconnecting lines for maintenance work, venting vapors from relief valves,

loading railroad tanks, truck tanks and drum filling.

The feasible controls which would eliminate and/or minimize workers' exposures from these leak sources are discussed below.

#### 1. Engineering Controls

*a. Use of dual system to facilitate purging MC before disassembling/disconnecting equipment for maintenance.* Because the production of MC employs a continuous and enclosed process, dual production components such as flow control valves and pumps are designed as an integral part of the production process. The use of dual production components is the key to continuous production processes, where bypasses to redirect the flow are used while maintenance is performed on specific components. The redirection of the flow is usually automated and very seldom requires physical contacts to the equipment by process operators. That is, when a signal from the process computer indicating equipment malfunction is received, the pump is automatically blocked off, and another pump is activated to replace the malfunctioning one. This is done by automated valves which employ an air actuator and shut automatically when given a signal from the computer. The employment of dual production equipment, is both a basic necessity for continuous production and contributes significantly to the reduction of workers' exposure. The reduction of workers' exposure is accomplished through the purging of production lines before disconnecting any equipment. This procedure will eliminate the release of any confined MC. The purged effluent is usually vented to flares for instantaneous burning.

Reduction of workers' exposure also depends on workers' training, and their ability to perform the purging process properly. This may entail testing the lines prior to disconnecting them, and disassembling the production components to be repaired.

*b. Scheduled preventive maintenance and continuous monitoring.* Scheduled preventive maintenance and prompt repairs have been proven to be feasible controls that limit the extent of workers' exposure. Restricting access to areas where leaks are likely to occur also limits workers' exposure. Regular inspection of equipment and transfer lines where leaks may occur is an additional step that can contribute to the reduction of workers' exposure.

Finally, continuous monitoring with an alarm system connected to the central control room would contribute to



the reduction of workers' exposure by alerting workers to the occurrences of leaks.

*c. In-line quality control sampling.* Sampling for quality control is another source of workers' exposures, if it is performed manually. Unlike manual quality control sampling, the in-line monitoring or sampling technique virtually eliminates workers' exposure to MC. In-line sampling equipment connected to analytical equipment such as gas chromatographs, are currently available and are being used at various production facilities. Further, the in-line sampling technique not only reduces exposure to sampling technicians, but also significantly reduces exposures to laboratory workers.

*d. Equipment modifications for drum filling.* Drum filling presents a more serious source of workers' exposure than that encountered during bulk loading (barges and tank truck loading). However, modifications can be made to the filling equipment, in order to reduce workers' exposure to MC. These modifications may include designing an exhaust jacket which surrounds the filling lance, in the form of two concentric pipes. The inner tube is used for filling the drum, while the outer tube functions as an exhaust conduit for the MC vapors. Further, refinement of the drum filling system can be achieved by constructing a drip pan to receive the drippings from the filling lance. The capacity of the exhaust system can be designed to control the vapors which escape from the filling lance, as well as those emitted from the drip pan. The exhaust jacket of the filling lance can be constructed from collapsible material (bellows type) resistant to MC (Ex. 7-209).

*e. Equipment modifications for bulk loading.* Slip-tube gauges are used to indicate the fluid level in tanks during bulk loading. Reduction of workers' exposure during the bulk loading process can be achieved through the use of magnetic gauges, in lieu of slip-tube gauges. The use of slip-tube gauges is undesirable. When slip-tube gauges are employed within a system, the operators are unnecessarily exposed to MC. Slip-tube gauges release a plume of the MC vapor into the air, when the liquid MC level reaches a predetermined point.

Magnetic gauges operate without the release of vapor into the air. Magnetic gauges function by transmitting the flow of motion by means of a magnetic coupling. A magnetic bond float gauge consists of a hollow magnet-carrying float which rides along a vertical non-magnetic guide tube. The follower magnet which is suspended by tape drives is an indicating dial similar to

that on a conventional tape float gauge. The float and guide tube, which come in contact with the measured fluid, are available in a variety of materials for resistance to corrosion, and to withstand high pressures or vacuum. Weighted floats for liquid-liquid interfaces are available. Magnetic coupling is frequently employed in level-sensing electrical switches. The integrated controls which would limit workers' exposures could be achieved when magnetic pumps are coupled with magnetic gauges (Ex. 7-221).

*f. Equipment modifications for pumps.* As indicated before, one of the major sources of workers' exposure is leaks from pumps (seals and glands). Since methylene chloride production is a continuous process, the use of dual equipment constitutes an integral parameter in the design and operational criteria.

Available information gathered during the field visit indicates that simple pumps allow escape of MC around the rotating drive shaft. Simple pumps employ seals consisting of compressed packing in a box around the shaft in the opening to the pump or tank. When the pumped fluid is free of particulates, as it is in the case of MC, mechanical seals can be used. Mechanical seals consist of two precisely machined annular metal faces which are mounted perpendicular to the shaft. One face rotates with the shaft, while the other is stationary. Pressure from the fluid in the pump in conjunction with the spring pressure, press the metal faces together, resulting in a good seal. These mechanical seals are known to be of better performance (less leaking) than pumps with packing. Mechanical seal pumps with dual or tandem seals are better than those with single mechanical seals.

Therefore, reduction of workers' exposure can feasibly be achieved through replacing simple pumps (employing packing) with tandem mechanical seals. Mechanical seal pumps are currently employed within the chemical processing industries. Due to the corrosiveness of MC to seals, the pumps normally require frequent maintenance. Excessive workers' exposure is usually associated with the frequent maintenance required for replacing seals of pumps (Ex. 7-202).

The performance of the magnetic drive pump is based on the complete isolation of the pumped liquid from the rotating shaft. In the design of the magnetic drive pump, the lack of seals and the complete separation between the motor shaft and the pump casing guarantee the total absence of leaks of the pumped fluid. That is, the magnetic drive pump consists of a wet end and a

dry end. The wet end includes the pump casing, impeller, shaft and the magnetic drive coupling which is supported with a bearing.

The magnetic driven coupling is the inner carrier which is sealed to the wet end. This sealing is a containment cell which is bolted to a housing with a gasket. The containment cell is made of a material with good electrical characteristics which is compatible with almost any solvent. Over the top of the containment cell is another housing, a secondary container. This secondary container, opens to the atmosphere for safety, through a shaft which is connected to the motor and is also sealed. The dry end consists of a bearing frame that supports a driver magnet carrier, which turns around in the containment cell. This is called the outer drive.

The magnetic drive pump operates with a conventional motor. The magnetic coupling converts the motor to the outer drive. The outer drive also consists of a shaft and standball bearings. This drive (dry end), which consists of outer magnets, excites the inner drive (wet end), and this mechanism provides the spin required for the pump to operate (Ex. 7-215).

The maintenance of magnetic drive pumps is simpler than that of seal pumps, hence making workers' exposure less frequent and of a smaller magnitude. Another advantage of the magnetic pump is its limited number of parts which renders its assembly and disassembly simple for repairs, and a short duration of task performance which affects the extent of workers' exposure. In summary, the unlikelihood of leakage, the low maintenance frequency and short duration of repair tasks, render the use of magnetic drive pumps ideal for the control of workers' exposure.

Finally, although it is not a major source of workers' exposure, leakage from corroded tanks and pipes, can feasibly be controlled. Corrosion protection can be achieved by using protective coatings and cathodic protection or corrosion resistant materials for construction. All of these approaches are technologically feasible, available and proven to be effective for achieving the intended goal.

## 2. Conclusion

Workers' exposure to MC has been controlled to below 25 ppm in most operations in MC production facilities through the use of the above indicated feasible means. However, information received by OSHA indicated that the highest exposure levels in the MC



production sector are obtained from the drum filling process. One facility visited by OSHA previously maintained 50% of the exposure levels below 50 ppm for this process. However, after modifications to the drum filling equipment, exposure levels were lowered to below 25 ppm. Finally, additional modifications to the MC production process such as the replacement of seal pumps with magnetic drive pumps would further reduce workers' exposure levels (Ex. 7-209).

#### B. Polyurethane Foam Blowing

There are two production stages during which MC is released into the work environment, both of which are sources of workers' exposure. The first stage of production, during which workers are exposed to MC, is pouring. As described in section IV, all ingredients (including MC and the various additives) are metered and fed into the mixing head through a closed system. The mix is then released into a trough which overflows onto a conveyor which is housed in a partially enclosed and ventilated tunnel. Foam production involves an exothermic reaction, and the water content in the mix affects the reaction temperature proportionally (more water results in higher heat output). If the heat output of the exothermic reaction is not properly controlled, a potential for a fire hazard in the pouring tunnel may become imminent (Ex. 7-207).

The second stage of production, during which workers are exposed to MC, is cooling/curing. In addition to MC's unique characteristics as a blowing agent, it is used as a cooling agent for dissipating the heat output that results from the exothermic reaction. The foam temperature, with the aid of the cooling effects of MC, can reach 300-330 °F. The percentage of MC in the mix that accomplishes both functions (blowing and cooling) ranges from 10-15% by weight for super soft foam and 2-3% for the firm foam. The control of workers' exposure in this industrial segment is discussed below.

#### 1. Engineering Modifications

a. *Pouring area.* During the first stage of production (pouring), approximately 50% of MC is released into the pouring tunnel. This amount of MC is exhausted through a mechanical ventilation system which consists of three blowers located in the ceiling of the pouring tunnel (Ex. 7-217).

The design and configuration of the exhaust system are of a simple type. Based on the information gathered during the site visit, OSHA has

determined that if the design parameters of the exhaust system are calculated and integrated properly, the MC concentration could feasibly be controlled to or below a 25 ppm exposure level (Ex. 7-217).

To verify and demonstrate the technological feasibility of controlling workers' exposure to MC vapors emitted in the tunnel during pouring, the following simple calculations are performed:

Annual Consumption of MC (pounds/year/facility) (Based on 750,000 pounds/8 facilities) = 93,750

Hourly Consumption (Based on 252 workdays per year and 4 hour work shifts per day) = 93 pounds/hour

50% Loss Rate during Pouring in the tunnel = 46.5 pounds/hour OR (0.775 pound/minute)

The volume of air required to dilute the MC in the tunnel so that the concentration does not exceed the 25 ppm level (assuming least efficient/dilution system)

$(0.775 \text{ lb/min} \times 456 \text{ g/lb} \times 24.5 \text{ L/mole} \times 10^6 \text{ ppm}) / (84.9 \text{ g/mole} \times 28.37 \text{ L/ft}^3 \times 25 \text{ ppm}) = 143,789 \text{ CFM}$

Based on the prevailing exposure levels, and since the specific operation visited had an exhaust system design capacity of 44,000 CFM, the system can be regarded as properly rated and designed to achieve approximately 81 ppm. Since existing available exposure data indicates that workers' exposure is centered around 75-90 ppm, it would be reasonable to regard the existing system as properly functioning according to its design criteria. However, if the system was designed to achieve the 25 ppm level, then it can be regarded as underrated by 69% of the appropriate capacity (assuming that the system is still functioning at its design capacity).

Several exposure levels collected over a number of years were provided by the firm which was visited by OSHA. Some of these exposure levels are difficult to assess for the unknown conditions under which the samples were collected. However, other exposure data provided are associated with a reasonable amount of information, which was considered during this technological feasibility assessment. These are listed as:

1. Breathing zone sample yielded an estimated 8 hour TWA exposure—(9/24/85 plant 1)—Range from 40-70 ppm.

2. Employee breathing zone sample collected before, during and after pouring, 8 hour TWAs were estimated, based on sample results and estimates of pre-pour, pour and post-pour—(4/14/87 plant 1)—Range from 9-28 ppm.

3. Employee breathing zone sample collected before, during and after pouring. Most employee eight hour TWA was estimated to be less than 50 ppm. Utility man and cut-off saw—(3/16/88 plant)—Range from 50-75 ppm.

4. Employee breathing zone sample—(5/18/87 plant 5)—Range from 4-38 ppm.

5. Employee breathing zone sample yields an estimated 8 hour TWA exposure of less than 100 ppm—(8/7/86 plant 6).

Average Range of the Above Representative Samples: 26-62 ppm (Ex. 7-207).

In this assessment, 20% was added to the above calculated range of exposures, so that the calculated levels resulting from the proposed modifications would be regarded as reasonable projections.

Since the tunnel has two open sides, each with approximately 12 × 6 ft (a total of 144 ft<sup>2</sup>), that allow make up air to exhaust the MC vapor, the face velocity at each open side of the tunnel should be approximately 1000 ft/minute, if the system is handling the 143,789 CFM. For the existing system which handles 44,000 CFM, the face velocity should be about 305 FPM.

It should be noted that the above calculation, demonstrates the technological feasibility of achieving the desired 25 ppm concentration of MC. This calculation was based on dilution ventilation which is the least efficient ventilation system. With the existing capacity of the system (44,000 CFM), the 25 ppm level can be achieved through minor modifications of the exhaust system inlets. Such modifications may include lowering the ceiling and/or changing the configuration and the location of the exhaust inlets (e.g. using a slot exhaust at the inner perimeter of the tunnel).

Another feasible control measure that would contribute to increasing the efficiency of the tunnel's exhaust system is the implementation of appropriate work practices. Because the temperature inside the tunnel is higher than that of the outside, and because the MC vapor density is almost 3 times that of the air, it is imperative that all access openings along the side of the tunnel are kept closed when they are not in use. This type of work practice would reduce or eliminate the dispersion and escape of the MC vapors outside the tunnel confinement, as well as maintain the drawing efficiency of the makeup air through the two openings (entrance and exit) of the tunnel. This work practice would also contribute to the reduction of exposures of workers who are stationed outside the tunnel.



During the site visit, it was observed that the operation of the cutoff saw released excessive MC vapor as a result of rupturing of the closed cells. A feasible control measure needed to reduce the exposure to the saw operator is to provide a slot exhaust system mounted on the guide tracks of the saw. This slot exhaust system would be connected to the exhaust conduit with a flexible hose to allow for the movement of the saw.

Another feasible alternative control measure for the cutoff saw operator and for the "paper pull" operator is to provide fresh air islands with a higher velocity and pressure than the remainder of the tunnel. Unless the air velocity of the fresh air island at the workers' breathing zone exceeds the MC contaminated air velocity inside the tunnel, the fresh air islands will be ineffective.

The control of MC inside the tunnel should be regarded as the principal approach for controlling workers' exposure in the remainder of the work stations (outside the tunnel). This assessment is based on the fact that 50% of the consumed MC is emitted in the tunnel within a 2-3 minute duration; while the other 50% of the consumed MC is emitted during 2-3 hours (rate of release of less than 1/100th of that in the tunnel).

*b. Curing and cooling stage.* After the foam (bun) moves outside the tunnel, a vacuum test is performed to determine the adequacy of the porosity needed to meet the customers' desired specification. The operator of the vacuum equipment is exposed to MC at a lower concentration than those operators who are required to perform their duties inside the tunnel.

Since the heat generation inside the bun (exothermic reaction) continues for almost 2-3 hours, cooling the bun (heat dissipation) is accomplished through a single layer stacking of the buns. Heat dissipation is accomplished through air movements between and surrounding the single layer buns. It was observed that no mechanical ventilation was provided in the building that was used for cooling the buns. Also, the building relied only on natural drafts from an opening approximately 80 ft wide which allows accessibility to the forklift. To control workers' exposure, the building should be provided with a mechanical dilution ventilation system having the same capacity as the tunnel's exhaust system. The following reflect the basis for the above system rating. The 50% of the MC consumed which is released during the curing and cooling stage (average 2.0 hours) is equivalent to 3.1 pounds per bun, or 11.8 grams per bun

per minute. Assuming a homogeneous rate of release during the entire 120 minutes cooling/curing time, the maximum rate of MC release during the time approaching the middle of the pouring duration (30 buns released from the tunnel) is 353 grams per minute. The volume of air per minute (air flowrate) required to dilute the 353 gm of MC to achieve the desired 25 ppm is:

$$(353 \text{ g/minute} \times 24.5 \text{ L/mole} \times 10^{-6} \text{ ppm}) / (84.9 \text{ g/mole} \times 25 \text{ ppm} \times 28.37 \text{ L/ft}^3) = 143.789 \text{ CFM}$$

The locations of the exhaust fans needed to exhaust the building should be distributed in a pattern compatible with the layout of the single layer bun, so that no stagnant air pockets would be created.

Since the two principal workers in the cooling/curing building are the crane and forklift operators, an alternative to providing a mechanical dilution ventilation for the entire cooling/curing building would be to equip the forklift and the crane with a ventilated enclosure provided with air cleaning devices. This alternative may be regarded as the preferred feasible control measure. This type of an enclosure is available and proven to be effective for a multitude of other contaminants. Without accurate and representative exposure data for the crane and forklift operators, a judgment cannot be made as to whether the building mechanical ventilation or equipment (forklift and crane) enclosures would be the preferred control method. However, either of these approaches is a technologically feasible control measure.

## 2. Substitution

MC is used in the production of flexible foam as an auxiliary blowing agent for the control of the foam's density. MC and Freon are comparable auxiliary blowing agents. From the production technology point of view, both MC and Freon would result in a faster foam rise, and hence produce a lighter or lower density foam. Currently, because of the ozone depletion phenomena, although Freon and MC are technologically comparable, MC is regarded as the environmentally preferred auxiliary blowing agent.

During OSHA's meeting with officials from the visited foam producer, it was indicated that the State of California is contemplating the adoption of Rule 1175 which compels the foam producer to totally eliminate the use of both auxiliary blowing agents (MC and Freon) by the year 1994. Further, this rule would require reduction of 40% of the MC emission by the end of 1990.

As a part of the plan to comply with Rule 1175 (if it becomes effective), the technological feasibility of chemical substitutes is currently being investigated by foam producers. One of the chemicals being considered for substitution is Aerolite AG (methyl chloroform) produced by DOW Chemical. Information on current foam production technology indicates that methyl chloroform can be regarded as a partial substitute or partial replacement for MC. Research is currently in progress to achieve the goal of total substitution.

Among other substitutes (partial) are Ortegol (produced by Goldschmidt Chemical), Geolite (produced by Union Carbide) and formic acid. Information gathered during the field visit indicates that Ortegol is regarded as a softening agent which results in reducing the volume of MC required to achieve the desired density. Geolite is only at the laboratory stage, and no information is currently available on its feasibility as a partial or total substitute.

The use of xylene in combination with an inert gas is regarded as another feasible substitute for MC. However, there are concerns for the technological limitations related to the release of unreacted TDI when the foam is crushed to open the closed cells. This crushing process is required for the production of more resilient foam (Ex. 7-207). Although no total substitute for MC is currently available, partial substitutes will reduce both the MC volume and its associated exposure levels proportionally.

## 3. Conclusion

Workers' exposure in the foam production facilities could be controlled through the use of available and feasible control systems. Although it is technologically feasible to provide dilution ventilation for the protection of the workers in the pouring tunnel, providing fresh air islands for each of the three tunnel workers (mixing head operator, cutoff saw and paper pull operator) may be regarded as the preferred control method.

Similarly, instead of mechanically exhausting/ventilating the cooling/curing building, providing a ventilated enclosure equipped with air cleaning devices may be regarded as the preferred choice for the control of the crane and forklift operators' exposures.

Both approaches are technologically feasible, however, no decision can be made with regard to the preferred control method for a particular facility without reliable, elaborate and representative exposure data. Since



partial substitution is feasible, it is reasonable to project that both the volume of MC consumed and its associated exposure levels will be reduced proportionally.

#### C. Aerosols

Methylene chloride is used as a solvent, co-solvent and vapor pressure suppressant in the aerosol manufacture. The advantages of using MC are included in the production technology section (IV). As mentioned previously, the feasibility of engineering controls for the reduction of workers' exposure depends mainly on the physical and chemical characteristics of the substance and its associated production or process technologies.

In the manufacture of aerosols there is only one major source of MC vapor emission which contributes significantly to workers' exposure to MC in this industrial sector. MC vapor is released when charging aerosol cans with liquid MC, using a metered injection pump. The injection tip is lowered into the can and the metered MC volume is then added to the paint mix in the can. The extent and magnitude of workers' exposure to MC during the can charging is a function of the area of the can's charging hole, the temperature of liquid MC, the time required to charge the can, and the capacity and efficiency of the exhaust system. Since the parameters influencing the extent and magnitude of workers' exposure are difficult to modify, with the exception of the MC temperature and the exhaust system's capacity, the assessment of technological feasibility will be focused on these two elements.

#### 1. Engineering Modifications

a. *Chilling MC.* For all practical purposes for this particular operation, MC concentration (workers' exposure to MC) is dependent on its vapor pressure (VP) which varies with temperature. At room temperature (20 °C/68 °F) the VP of MC is 355 mm Hg. With a slight rise in MC temperature (e.g. 5 °C), the vapor pressure increases to 450 mm Hg. Therefore, it is reasonable to predict that workers' exposure can increase by 27% as a result of increasing the MC temperature 5 °C (from 20 °C to 25 °C).

Since the freezing point of MC is -142 °F (-97 °C), controlling workers' exposure, through lowering the vapor pressure (cooling or chilling the liquid MC) before charging the can, extends over an 100 °F temperature range. An incremental or slight decrease in the temperature of MC will result in a proportional decrease in workers' exposure to MC vapors.

The vapor pressures associated with lower temperatures clearly demonstrate the extent of reduction in workers' exposure (provided that all other variables remain unchanged). For example, at 77, 68, 20, -8 and -28 °F, the vapor pressure is 450, 355, 100, 40 and 20 mm Hg, respectively. It is clear that a moderate chilling effect (lowering the MC temperature from room temperature of 77 °F to 20 °F) will result in lowering its vapor pressure by 75% (to less than 25% of its VP value at the room temperature). That is, it is reasonable to project that a reduction of workers' exposure equivalent to 75% will be achieved as a result of passing the liquid MC through a chilling coil designed to attain 20 °F before charging the can.

The chilling coil can be incorporated within a heat exchanger, where both the coil and the exchanger are made of a non corrosive material (i.e. stainless steel). In such a process, the MC will flow through the coil and be chilled within the heat exchanger, where the "reservoir" of the heat exchanger is a separate unit, namely a chiller. The chiller can be made out of aluminum since it only contains a glycol-water chilling solution which will be pumped into the heat exchanger to allow chilling of the MC vapors that flow through the stainless steel coil. This process of chilling the MC vapors is technologically feasible.

Certain chillers are designed to meet a wide range of capacities on an instant demand from zero to 100% capacity. This flexibility can be accomplished by a means of incorporating a dual pump arrangement and storage reservoir which is standard on a variety of chillers. At maximum demand, (100% capacity) the chiller fluid flows from the storage reservoir, to the system pump, to the load and back through the recirculating pump, then through the chiller evaporator and into the reservoir. On a zero load, the fluid bypasses the cooling load system, short circuits through the bypass check valve which opens on a change in pressure differential, and then flows through the recirculating pump, the chiller evaporator and into the storage reservoir.

Evidence in the record, Exhibits (7-204 and 7-214), indicated that chilling systems for lowering liquid MC temperature are technologically feasible and available. A chilling coil having the capacity of lowering the MC temperature from 77 to 20 °F, at a rate of 220 g/s, (approximately 30,000 BTU/hr)<sup>1</sup> will result in lowering the MC vapor pressure and its associated exposure levels, by more than 75%.

Since field gathered information indicates that the majority of current exposure levels range from 11 to 67 ppm (with the exception of non-detectables and outliers<sup>2</sup>), with the use of a chilling coil to lower the MC temperature to 20 °F, workers' exposure levels can be expected to decrease proportionally by 75% (exposure levels will range from about 3 to 17 ppm). This reduction in current exposure levels is based solely on lowering the temperature from approximately 80 °F to 20 °F. That is, further reduction in MC temperature, coupled with improvement in the capacity and configuration of the exhaust system, will result in much lower exposure levels.

b. *Exhaust system modification.* In addition to the chilling approach, workers' exposure can also feasibly be controlled through minor modifications or improvement in the capacity of the current exhaust system.

Information gathered during the field visit indicated that currently, each of the three injection pumps of the three operating charging conveyors, is provided with an exhaust system consisting of a slot hood with an area of approximately 2" high x 6" wide (0.083 sq ft). Since the current exposure levels, as indicated before, range from 11 to 67 ppm, simple extrapolation indicates that increasing the volume of air currently exhausted will result in a proportionate reduction of the prevailing workers' exposure levels. In other words, if the volume of air is increased to 3.5 times that of the current exhaust volume, the current exposure level is expected to decrease proportionally, to below 25 ppm.

Since the area of each slot is only 0.083 sq ft (total of less than 0.25 sq ft for the 3 slot hoods), the required amount of exhaust air cannot be regarded as significant. Based on field experience and professional judgement, the face or slot velocity was not even close to 50 fpm, when the exposure level ranged from 11 to 67 ppm. Therefore, achieving a predetermined exposure level can be proportionally extrapolated. Using the upper range of the exposure level of 67 ppm, increasing the exhaust volume of air by 3 times, will reduce workers' exposure to below 25 ppm. The volume of air required to achieve the above intended reduction can be quantified to equal  $3 \times 0.25 \text{ sq ft} \times 100 \text{ fpm} = 75.0 \text{ CFM}$ , a minimal increase in air flow.

Further modifications can be made to the configuration of the slot exhaust system, such as but not limited to, enlarging the dimensions of the slot so that a larger area (surrounding the can being charged with MC) can be



exhausted. This modification would increase both the volume and velocity of the exhaust air. It is noteworthy to mention that direct drive exhaust fans are more efficient because they are not subject to belt slippage.

*c. Enclosing the conveyor.* All of the components used for charging and filling the aerosol cans are assembled on a conveyor (approximately 15 ft long and 2 ft wide). The height of the equipment used for valve assembling, crimping and injection pumps (for the paint or MC) is approximately 3 feet. A simple enclosure for the conveyor can be installed and exhausted through a downdraft plenum to be located before the explosion-proof room. This is a feasible means for lowering workers' exposure to MC.

The volume of air required to exhaust the conveyor enclosure is 4500 CFM (assuming homogenous MC concentration in the conveyor enclosure (15×2×3 ft), and having 50 air changes per minute). Since workers' easy accessibility to the injection equipment is highly desirable, the enclosure can be made of overlapping flexible plastic strips. The same overlapping flexible plastic strips can be used at both the entrance and exit sides of the conveyor provided that an allowance or an opening for the can movement is incorporated. It is needless to indicate that this simple control approach will not only provide for workers' protection against excessive MC exposure, but will also provide protection against exposures to other volatile substances contained in the paint formulation. Additionally, the flexible plastic strips will result in reducing workers' exposure to noise generated by the conveyor, injection pump and other assembly equipment.

## 2. Substitution

Another feasible method of controlling workers' exposure to MC is substitution. A non-MC combination (methyl chloroform, acetone, a hydrocarbon propellant and pigment solvent) is currently available and in use. However, research is still in progress to achieve more technologically efficient non-MC substitutes.

## 3. Conclusion

The above assessment demonstrates the availability and feasibility of engineering controls that would limit workers' exposure to MC vapors during the aerosol manufacturing process.

## D. Polycarbonate Resin

MC is used as a process solvent in the production of polycarbonate resin. It is a true process solvent and it does not

enter into the reaction. Out of a 1,700 person workforce, only 60 workers are exposed to MC.

Polycarbonate resin is produced in an enclosed system using a continuous process as described in the process description section. Most components of the production equipment are located outdoors. Therefore, leaks from gaskets, pipe couplings, pumps, valves, sampling ports, etc. are diluted and dispersed into the atmosphere. Consequently, exposure of workers to MC is minimized, as documented in the record, Exhibit 7-203. The mean concentration levels of MC in 1988 and 1989 (16.0 and 18.3 ppm, respectively) are the result of implementing several feasible control measures such as, column dryer technology, upgrading the solvent recovery system, installing MC rupture disk alarms, substituting standard seals with Teflon seals, upgrading the ventilation system of analytical facilities, installing magnetic relief valves, and upgrading the automated instrumentation to allow off-site (control room) observation of the Lexan production.

Because of the automation of this production system, workers spend very little time in the field (in the vicinity of production equipment) and the majority of their time is spent in the control room where no exposure to MC exists.

As indicated before, sources of workers' exposure to MC in the production facilities of polycarbonate resin are limited to leaks from processing equipment, piping, valves, tanks, towers, and pumps. However, the two main sources of occupational exposure to MC are quality control sampling and scheduled/unscheduled maintenance, which includes the changing of filters (Ex. 7-203).

In the production of polycarbonate resin, most quality control sampling is done by opening valves and draining the viscous solution to flush the line before samples are taken. There are approximately fifty discrete points of sampling. Quality control sampling is performed manually because available automated or in-line sampling devices have only the capability of monitoring chemical characteristics and not physical properties. Polycarbonate quality control samples must undergo physical property testing such as optical density.

Currently sampling ports are equipped with open top buckets to capture the flushing solution that must be drained before the quality control specimens are sampled. This method permits the operator to observe and monitor the flushing of the sampling lines. The buckets are also used to capture any

dripping or leaks from valves after sampling is completed.

The second source of worker exposure is during filter change, which is regarded as routine or scheduled maintenance.

## 1. Engineering Controls

*a. Quality control.* Reduction of workers' exposure can be achieved by installing in-line sampling equipment at the various locations of the production facilities. This method of control will limit the number of times that sampling is done in one day. Information gathered during the field visit indicates that the number of manual sampling times per shift will be reduced from 25 to only 1 time which is necessary for testing the optical properties of the polycarbonate resin.

Reduction of workers' exposure during the manual sampling, which is required for testing the optical properties, can be achieved by providing a cover for buckets equipped with a receiving funnel having an elbow in the stem. After sampling, a small aliquot of water can be used to provide vapor blockage at the elbow. If water is added to the bucket and is used to flush the funnel and fill in the elbow, MC vapors will be confined, and workers' exposure would be extensively reduced. This type of modification is simple, can be designed and built on site, and requires no mechanical ventilation.

*b. Waste transport.* Workers' exposure during waste transport is the result of flushing fluid in buckets used for manual sampling. This exposure can feasibly be reduced through the use of portable and enclosed waste tanks. These portable and enclosed waste tanks could be mounted on dollies, and equipped with funnels having an elbow trap in the stem, similar to the one described above. These portable waste tanks could also be provided with a port to pump the contents to the formulation tank through a closed system, in lieu of the current open dumping practice.

## 2. Maintenance

*a. Unscheduled maintenance.* Several pieces of equipment are available to significantly reduce the frequency of performing unscheduled maintenance tasks, and consequently, reduce workers' exposure. These include sealless pumps and magnetic valves which can be employed within the polycarbonate resin operation. These pumps and valves do not require frequent maintenance, and consequently limit workers' exposure to MC. Reduction in maintenance frequency will not only contribute to the reduction of workers' exposure to MC, but will



also reduce exposures to other chemicals associated with the production of polycarbonates.

A sealless pump that can be employed is the magnetic drive pump. OSHA realizes some of the limitations on the use of the magnetic drive pumps. Polycarbonate resin production involves pumping high volumes (e.g. 150 gpm) of viscous fluid and at high pressures (e.g. 450 psi). Current technology indicates that no magnetic drive pump is available that has a capacity to move a viscous solution with a pressure of 400 psi and a flowrate of 150 gpm. However, the magnetic drive pumps can be used for several operations involving lower pressures and/or flow rates than those indicated above.

Scheduled preventive maintenance and prompt repairs, restricting access to areas where leaks are likely to occur and regular inspection of equipment where leaks may occur are additional feasible steps that can contribute to the reduction of workers' exposures.

*b. Filter replacement (scheduled maintenance).* Another source of workers' exposure to MC occurs during the replacement of vacuum filters. The current practice is to purge the vacuum filters before they are replaced in order to remove any MC and thereby limit workers' exposure. Although the purging technique is effective, additional reduction of workers' exposure can be achieved through designing a portable canister that can confine the spent filter components. The current practice of leaving the spent filters exposed during the installation of the new filters can not be regarded as an acceptable practice. This canister, since it does not incorporate any sophisticated engineering design or mechanical ventilation, is a technologically feasible control technology.

### 3. Conclusion

Although available information indicates that workers' exposure is far below the proposed 25 ppm limit, further reduction could be achieved through the implementation of available and technologically feasible control measures. Workers' exposure during quality control sampling could be reduced through the design and use of covered waste containers provided with a water filled elbow as a vapor trap. The same principles could be used for designing waste transport containers along with a facility to pump the waste directly to process tanks, instead of the direct dumping practice. During scheduled filter replacement, the use of a closed canister to confine the vapor being emitted from the spent filter would contribute to the reduction of workers'

exposure. Since prevailing exposure levels are currently below the 25 ppm proposed limit, no modification of engineering controls would be necessary for the promulgation of the 25 ppm limit. Data gathered during the field visit indicated that exposure levels achieved within the last 3 years ranged from 16.0 to 4.5 ppm, with 4.5 ppm being the prevailing level during 1990. OSHA is confident of this assessment since exposure data were measured by two independent methods.<sup>2a</sup>

Finally, although substitute solvents, such as ethylene dichloride, are available for the production of polycarbonate resin, they are not desirable because of their flammability characteristics. Therefore, it is not necessary to assess the feasibility of substitutes at this time (Ex. 7-203).

Based on this assessment, OSHA determined that there would be no additional engineering controls or modifications needed for the purpose of complying with the proposed standard, since current exposure levels are below 25 ppm.

### E. Pharmaceuticals

The use of MC in the pharmaceutical industry started in the 1970's at which time it was used as a substitute for isopropyl alcohol and carbon tetrachloride. MC was the choice solvent in pill coating because of its good solvency properties, fast rate of drying (evaporation) and safe handling. Because of the recent health concerns of MC, the pharmaceutical industry has already developed an aqueous coating formula. However, MC is expected to be used in pill coating for several years until all of the necessary data required for obtaining the approval of the Federal Regulatory Agency (i.e. FDA) are secured (Ex. 7-229).

In pill coating, there are five production stages during which MC is released into the air, thus contributing to workers' exposure. The first stage is the coating media formulation which consists of two successive steps, mixing the ingredients and preparing the homogenizer. Workers' exposure during the first step is caused by the addition of MC, into a 1000 gallon mixing tank which contains the various ingredients of the coating formula. The mixing tank is provided with a feeding port approximately 2 feet in diameter. A half circle portable exhaust slot (2 inches x 18 inches) equipped with a flexible hose connected to the main exhaust blower is used to control the MC emission during the feeding of the coating ingredients into the mixing tank.

Workers' exposure during the second step is caused by the stirring of MC

during the preparation of the homogenizer formula. The ingredients of the homogenizer formula (titanium dioxide and talc powder) are slowly and manually added to a pan containing MC. The mix in the pan is mechanically stirred. The addition of the homogenizer components and the stirring process takes place in an open face hood (5 sided hood) equipped with a 4 inch exhaust takeoff. The exhaust port is located at the back of the hood. The two 1000 gallon mixing tanks and the homogenizer hood are interconnected and exhausted by one blower.

This exhaust blower operates at 800-2,500 CFM depending on the number of tanks being used during one time. That is, if one mixing tank is used, the exhaust volume would be rated at 2,500 CFM. On the other hand, if both mixing tanks and the homogenizer hood are operated simultaneously, the exhaust volume at each of these three pieces of equipment would be rated at approximately 800 CFM.

Normally, the above two steps are performed successively. However, exposure data are compiled together without indication as to whether one or more of the three pieces were in simultaneous operation. Therefore, differentiation between the independent contribution of each source could not be made. The combined exposure levels during the performance of these two steps were ranging from 4 ppm to 124 ppm, with an arithmetic mean of 54 ppm. It is worth mentioning that the exposure levels prevailing before the installation of the above described exhaust system ranged from 7 to 218 ppm, with an arithmetic mean of 67 ppm (Ex. 7-228).

The second stage of the pill coating operations consists of the gravity filling of the 40 gallon drum with the already mixed and homogenized coating formula, which is contained in the 1,000 gallon mixing tank. The current drum filling technique relies on the operator's attention in watching the movement of the float's stem. Without concerted efforts on the operator's part, overfilling the drum is apt to occur, unnecessarily exposing the operator and other workers, who are stationed in the vicinity of the drum filling station, to MC vapors.

The third stage of the pill coating operation consists of two successive steps. During the first step, the filled drum is stirred to ensure complete homogenization of the coating media. Currently, the stirring is performed without using exposure control measures. This practice requires the unsealing of the drum by removing the tape and the drum cover, and



substituting the cover with another cover. The latter cover is provided with a notch to permit the insertion of the mixer.

The second step consists of pumping the coating media to a 5 gallon bucket. Following the completion of the stirring process, the coating media is pumped to a 5 gallon bucket which has a loose lid. This bucket, also, is not provided with any ventilation or control system. The combined emission from both steps (i.e. stirring the drum contents and filling the bucket) results in exposure levels ranging from 1.7 to 2.4 ppm, with an arithmetic mean of 2 ppm.

The fourth stage is the actual spraying of the coating media inside the coating pan. This stage is regarded as a closed system and has insignificant contribution to workers' exposure.

The fifth stage consists of flushing and purging the transfer lines and the pneumatic pumps with MC. This stage is regarded as the most significant source of workers' exposure. During the performance of this stage, workers are exposed to 138 ppm of MC.

#### 1. Engineering Controls

*a. Mixing process*—i. Addition of main ingredients. As indicated above, exposure levels before the implementation of the current local exhaust system were ranging from 7 to 218 ppm with an arithmetic mean of 67 ppm. After the implementation of the current exhaust system, the range of prevailing exposure levels were lowered to about 1/2 the old levels (4–124 ppm) with an arithmetic mean of 54 ppm. The current exhaust system is equipped with one blower which is interconnected to the three pieces of equipment (i.e. 2 mixing tanks and the homogenizer hood), having an exhaust capacity ranging from 800–2,500 CFM. Reduction of the prevailing exposure levels can be accomplished by three various means (Ex. 7–228).

The first option is to implement strict and appropriate work practices prohibiting the operation of the three pieces of equipment simultaneously. This will result in dedicating the total system capacity (2,500 CFM) to the one piece of equipment, hence the prevailing exposure level would be expected to be reduced to 1/3 of its current value (i.e. 1/3 of 54 ppm or 17 ppm).

The second option is recommended in case the production protocols call for the necessary operation of the 3 pieces of equipment simultaneously. In this case, each of the two mixing tanks and the homogenization hood would need to be exhausted separately, by independent blowers. Therefore, two additional blowers of the same capacity

(i.e. 2500 CFM) would need to be added. This modification would result in having an independent blower for each of the two mixing tanks and the homogenization hood. Therefore, the prevailing exposure levels are expected to be lowered to 1/3 of their current values if these equipment are operated simultaneously.

The third option is to modify the chiller's cooling capacity of the water jacket that surrounds the mixing tank. Currently, the chiller has a capacity of lowering the temperature of the water in the cooling jacket to 40 °F. If the cooling water temperature is lowered to 20 °F, the vapor pressure (VP) of MC will decrease by 59% (from 220 mm Hg to 89 mm Hg). This will result in an approximate proportional decrease of the MC concentration (i.e. from 54 to 22 ppm).

*ii. Addition of homogenization ingredients.* In addition to the above indicated approaches of providing an independent exhaust blower to the homogenization hood, and/or avoiding its simultaneous operation along with the mixing tanks, further reduction of MC vapors released during the homogenization process can be achieved through simple and minor modification to the current five sided open hood. This modification may include providing the front side of the hood with a curtain made of flexible strips, (disposable material), or can be made of a sliding glass (sterilizable material) door to provide the needed accessibility to the homogenization pan. The above modification will increase the face velocity of the hood and reduce its exposed surface area, and therefore, increase the exhaust efficiency of the homogenization hood.

*b. Drum filling.* Modifications to the current technique of gravity filling of the drums can be achieved using modern filling devices equipped with automatic shutoff valves. In addition, the current drum filling technique uses a notched drum lid which acts as an open source of MC vapor release from the drum during the filling stage. Examples of these modern filling devices are described in detail in the section on "MC Production". If a modern filling device is used, the current need for the tape sealing of the drum lid will be eliminated. OSHA realizes that minor modifications to the filling port of the drum lid will be needed. These modifications will be needed to accommodate the insertion of the mixer's blades that are required for the stirring of the drum contents (before transferring the coating media to the coating pans). These modifications will not only reduce or eliminate the

potential for overfilling the drum, but will also eliminate the need for the operator to stand at a close proximity to the drum being filled.

OSHA realizes that even with the deficiencies described above, the exposure levels were ranging from 13–14 ppm. If these levels are representative of workers' exposure during all times, none of the above technologically feasible control approaches would need to be implemented. However, the above feasibility determination is intended as a broad approach for reducing prevailing exposure levels to the maximum technologically feasible extent.

*c. Stirring and transferring coating media.* As indicated above, in the coating department there are two potential sources of exposure. The first source is the result of stirring the drum contents to ensure the complete homogenization of its contents. The second source is the result of pumping a predetermined aliquot of the coating media from the drum to the five gallon bucket. Current exposure levels resulting from the combined two sources do not represent potential concerns because they are ranging from 1.7 to 2.4 ppm with an arithmetic mean of 2 ppm. However, the techniques employed during these two steps result in unnecessary exposures, although they appear to be of insignificant magnitude.

*d. Spraying the coating media.* The potential source of workers' exposure during this stage is the result of spraying the coating media inside the coating pan. The total consumption is 104 pounds of the coating media, which contains 67.7% MC, per hour, or 70.4 lbs MC per hour. This amount is consumed/sprayed in five pill coating pans, yielding 31 liters of MC vapor/min per pan. The exhaust system of each pill coating pan is rated at 1,150 CFM and operates at 4" H<sub>2</sub>O negative pressure, yielding a concentration of approximately 950 ppm in the exhaust effluent.<sup>3</sup> This negative pressure is judged to be of a magnitude which is sufficient to prevent leakage from the pan into the work environment. Therefore, it is not reasonable to recommend increasing the air volume of the current exhaust system.

In summary, exposure levels measured in the vicinity of the coating pans are expected to be generated primarily during the flushing of the transfer lines and the associated pneumatic pumps, and secondarily during the mixing of the coating formula while in the drum (before transfer to the 5 gallon container). An additional and insignificant contributing exposure



source is generated during the injection cycle from the loosely covered 5 gallon containers. Since the coating pan is equipped with an exhaust system having a rating of 1,100 CFM input and 1,150 CFM output and operating at 4" H<sub>2</sub>O negative pressure, OSHA believes that these operating conditions would not result in any appreciable contribution to workers' exposure. Therefore, no engineering modifications are recommended (Ex. 7-228).

*e. Flushing transfer lines and pneumatic pumps.* The most significant source contributing to workers' exposure is the flushing of both the transfer lines and the pneumatic pumps. Exposure levels measured were 138 ppm. Currently, flushing the transfer lines and the pumps takes place in the coating room with no exhaust system provided to confine the vapors of MC. Therefore, providing an enclosure to house the flushing system and the containers holding the flushing solvent (MC) would be the appropriate and technologically feasible control. The enclosure could be of a simple design such as a 5-sided hood provided with a blower having a capacity of 500 CFM. The blower can be connected with a flexible or rigid duct to the downstream side of the existing coating pan blower.

The 500 CFM blower rating would maintain a minimum face velocity of 80 fpm in a hood having approximately a 2x3 ft face opening. This size of the hood's face would be sufficient to accommodate the equipment to be flushed as well as housing the 40 gallon drum, although exposures from this latter source as discussed above, were determined to be of an insignificant magnitude.

Further, the 80 fpm face velocity, is sufficient to exhaust the vapors emitted during the flushing cycle and expected to yield exposure levels below 25 ppm. OSHA realizes that makeup air passes through HEPA filters, and engineering discretion should be exercised to maintain the exhausted air volume to a minimum. However, since the flushing cycle takes place very infrequently and for a very short duration of approximately 19 minutes/shift, OSHA does not expect that the exhaust blower will be operating for any extended duration beyond the necessary time. That is, the 500 CFM blower will be operated for approximately 15-30 minutes per shift totaling a maximum of 15,000 ft<sup>3</sup> per shift. Consequently the current volume of makeup air, that is being provided through the HEPA filter, needs to be supplemented by 15,000 ft<sup>3</sup> per shift.

## 2. Conclusion

Achieving exposure levels of 25 ppm or below has been demonstrated to be technologically feasible in this industrial segment. There are two operations that need to be modified by the above described feasible engineering and work practice controls. The first operation is the mixing of ingredients (i.e. adding the formula ingredients in the main mixing tank and adding the homogenization ingredients in the pan). Achieving 25 ppm for these combined operations could be accomplished by two feasible options.

The first option is to implement strict work practice procedures to prohibit simultaneous operation of mixing equipment. That is, dedicating the available exhaust volume of 2,500 CFM to one piece of equipment at any one time. To achieve this objective, the system should be provided with gates to redirect the exhaust flow to the desired piece of equipment.

The second option is to provide two additional blowers to ensure that each piece of equipment (two mixing tanks and homogenization hood) will have its own independent exhaust blower in case that production protocols require simultaneous operation of more than one piece of equipment.

The second operation requiring engineering modification is the flushing of the transfer lines and the pneumatic pumps. Exposure control was determined to be technologically feasible through providing an enclosure equipped with an exhaust blower rated at 500 CFM.

## F. Manufacturing of Paint and Paint Removers/Strippers

The main solvents currently used in paint formulations consist of mineral spirits (petroleum naphtha products). Mineral spirits are not used for the purpose of removing paint or as paint/varnish removers due to their inability to penetrate the cured layer of paint efficiently. That is, once a coat of paint is applied, it reacts with oxygen and forms a cross-linking mechanism. The paint then becomes a much tougher polymer, and so the same solvent used to formulate the paint (e.g. mineral spirits), can not be used to remove the paint (Ex. 7-219).

Currently, MC is not used as a solvent in the manufacturing of paint because of its undesirable lifting properties. That is, if MC is used in the formulation of paint and fresh paint is applied over an old coating, the MC in the fresh paint would lift up or "remove" the old coating. This is due to the immense solvent potency of MC. The resulting coat of paint would

be undesirable in terms of texture and static appearance. Therefore, MC is currently being used more frequently as a paint/varnish remover (Ex. 7-219).

MC is used as a solvent in the varnish remover formulation and paint remover (stripper) formulation because it has the ability to separate the substrate from the coating system. The paint and varnish remover formulations are similar in terms of MC content since both consist of approximately 70% MC in their formulations. Methyl chloroform, CFC and any combination of dibasic esters are regarded as substitutes for MC, but none possess the desirable penetration characteristics of MC (Ex. 7-219).

Two production methods, the single batch manual mix and the multiple ingredient mix, are used to prepare paint varnish removers and paint stripping formulas. The following is a description of the controls that are currently used for each production method. The first method (i.e., single batch manual mix) is used for the manufacture of paint varnish removers. The second method (i.e., multiple ingredient mix) is used for the manufacture of paint stripping formulas. This second method involves the pumping of multiple ingredients through a piping system designed to eliminate the manual handling of the ingredients. Ingredients are stored in tanks located outdoors and are equipped with mixing platforms and steam cleaning lines (Ex. 7-219, 7-218).

## 1. Engineering Controls

*a. Single batch mix method.* As indicated previously, the production method for varnish removers is a single batch mix process, in which the components or the ingredients are normally added manually to the mixing tank with the exception of MC which is pumped and metered directly into the tank.

The mixing tank is usually located in a partially open area (3 sided canopy). The tank is provided with a 2 x 2 ft opening with a hinged cover. The workers' exposure duration is limited to the time required to manually add the ingredients into the tank (e.g., cellosic thickener). However, since no worker is required to be stationed at a close proximity to the mixing tank, appropriate work practices are determined to be of critical importance. Leaving the tank opening uncovered during the mixing process creates an unnecessary source of exposure. It was indicated, during the OSHA site visit, that exposures at this location as measured by a 3M organic vapor monitor revealed 89 ppm (TWA) when a



70% MC formulation was being processed.

Workers' exposure in this paint varnish remover formulation facility is limited to two sources. The first source is generated during the manual addition of ingredients into the mixing tank. The second source is generated during packaging (filling the cans) on the conveyor.

In order to reduce workers' exposure from the first source (mixing tank), local exhaust in the form of a two sided slot hood needs to be installed to trap the MC emission from the feed opening of the mixing tank. An alternative to this is to provide a ventilation system in the form of a fresh air island, at the platform on which the tank operator stands. This system would reduce workers' exposure when the tank is opened for adding ingredients or performing other tasks. In either case, strict adherence to good work practices should be maintained.

Good work practices may include, but are not limited to, keeping the tank cover closed during mixing, and instructing the operators not to lean over the tank when ingredients are being added (Ex.7-219).

A double sided slot hood is a technologically feasible method for controlling workers' exposure at the platform of the mixing tank. The current reliance on wind effects (dilution or dispersion of MC emission) as a control practice can not be regarded as an acceptable method for limiting workers' exposure. The feasibility of controlling workers' exposure through providing mechanical ventilation (e.g., a double sided slot exhaust hood) can be demonstrated through calculating the volume of exhaust air required to achieve the desired reduction in workers' exposure.

$$Q = 3.7 \times 4 \text{ ft (length of slot)} \times 100 \text{ FPM (V)} \\ \times 1 \text{ ft (centerline for 2 ft tank opening)} \text{ or} \\ 1,500 \text{ CFM total}$$

Workers' exposure at the can filling conveyor can be controlled by installing an enclosure in the form of a canopy made of flexible plastic strips so that workers maintain their accessibility to the can's filling equipment. Since the filling of the can takes place on an open conveyor which is approximately 15 ft long by 2 ft wide, and the height of the filling pump is less than 3 ft high, and since the MC vapor is approximately three times heavier than air, a simple enclosure for the conveyor can be installed and exhausted through a downdraft plenum. This is a technologically feasible means for lowering workers' exposure to MC at this location.

The volume of air required to exhaust the conveyor enclosure (assuming homogenous MC concentration along the total length of the conveyor) can be approximated by  $Q = 15 \text{ ft} \times 2 \text{ ft} \times 3 \text{ ft} \times 50 \text{ air changes per minute} = 4,500 \text{ CFM}$ . As indicated before, to accommodate workers' easy accessibility to the filling pump, the enclosure can be made of overlapping flexible plastic strips. These strips can be used at both the entrance and the exit sides of the conveyor provided that an allowance or an opening for the can movement is incorporated. This flexible and simple enclosure will not only provide for worker protection against excessive MC exposure, but will also provide protection against exposure to other volatile substances contained in the paint remover formulation.

Additionally, the flexible plastic strips will result in reducing workers' exposure to noise generated by the conveyor, filling pump and can sealing equipment.

**b. Multiple ingredients mix method.** As indicated previously this second method is used to manufacture paint stripping formulas. In this method, the mixed formula is prepared by simultaneous pumping of the various ingredients. After mixing is completed, the mixed formula is pumped into an open tank which is located indoors. The filling tank, which was observed by OSHA during this site visit, is currently not provided with any controls or a cover. One of the reasons indicated for not covering the tank is the need for the operator to continue monitoring the level of the fluid (paint stripping media) to ensure a continuous supply to the filling lances (Ex.7-218).

Reduction in workers' exposure, resulting from MC vapor escaping from the open tank, can be achieved by providing the tank with a valve and a flotation device. These devices are to be connected in a series with the main pump. Whenever the fluid drops below a certain level, the valve will open, and replenish the consumed fluid. These simple devices will eliminate the need for the operator to physically monitor the fluid level in the tank. Consequently, there will be no need to maintain the tank uncovered.

Further reduction of workers' exposure, especially during the hot weather, can be achieved by providing the tank with a heat exchanger and a chilling coil. OSHA realizes that the tank temperature cannot be lowered extensively, since lowering the temperature will result in increasing the fluid viscosity. This may render the fluid to be too viscous to be pumped. However, in the summer months where the temperature can exceed 100 °F,

chilling the tank to 68 °F will result in significant reduction of MC evaporation rate. Reduction of the temperature from 100 °F to 68 °F will be associated with reduction of MC vapor pressure from approximately 690 mm Hg to 350 mm Hg. Consequently, this will result in the proportional reduction of workers' exposure (i.e., approximately 50%) without affecting the ability to pump the fluid.

## 2. Conclusion

The above assessment for both production methods reflects the availability and technological feasibility of engineering controls that would limit workers' exposure to MC vapors during both steps (i.e., mixing and canning).

## G. Paint Stripping

Three methods are used in the furniture stripping industry, the flow-on system, the hand application, and dip tank method.

Each method has unique characteristics, and therefore, workers' exposure and their associated controls vary significantly.

### 1. Engineering controls

**a. Flow-on system.** The standard size of the MC tank for the flow-on operation is 10' x 4', with a slight decline to allow stripping fluids to be channeled through a drainage trough back into a storage container for reuse. Usually, ventilation is achieved through a local exhaust system provided with four slots, one located at each side of the tank (Ex. 7-231).

Stripping fluid (72% MC) contains paraffin wax added as a retardant to lower the evaporation rate of MC (Ex. 7-231). As observed by OSHA during the site visit, workers' exposures occur during the performance of the following successive tasks.

During the first task, stripping fluid is pumped from a 55 gallon drum to a four gallon holding can, by placing the applicator brush into the drum and pumping the fluid into the can. The fluid is then pumped from the four gallon can to a brush applicator. After applying the fluid with the brush applicator, a few seconds are allotted for solvent penetration and blistering of the paint.

During the second task, the operator uses a putty knife to scrape the paint or varnish from the furniture. Some stubborn paint may require the use of additional coats of stripping fluid and/or the use of a wire brush or steel wool to expose the wood grain.

During the third task, the operator uses a squeegee to push the excess stripper and the waste that was



removed, down through the drainage port in the tank and into the trough, where it is collected back into the four gallon can for recirculation. Through the recirculation, the stripping fluid is continually used, until it reaches a heavy consistency that renders its usefulness for the removal of paint or varnishes obsolete. The consumed stripping fluid is stored in unsealed containers provided with a large hole cut out of the top to allow the stripping fluid to drain into it. The stripping fluid that was previously used for varnishes is reused to strip painted furniture. At any one time there may be as many as three or four such containers being stored under the stripping tank at a close proximity to the worker (Ex. 7-231).

At one of the facilities visited by OSHA, a 10' x 4' table was provided with an exhaust system with a capacity of 1,500 CFM. According to established and published engineering design criteria, this exhaust system handles approximately  $\frac{1}{3}$  to  $\frac{1}{4}$  of the appropriate capacity (if the 125 CFM/ft<sup>2</sup> is used as recommended in the design criteria). This design criteria yields 67 fpm capture velocity, which is very close to the minimum velocity required for operations releasing vapors with practically no velocity. OSHA's assessment is based on published data indicating that 50 fpm is the minimal capture velocity for vapors in lateral hoods in undisturbed locations. It would be reasonable to consider the movement of the operator at the table as a source of a slight draft, for which an additional 10-25 fpm increase in the capture velocity would be desired. Therefore, 60-75 fpm capture velocity is needed for this type of system. Clearly, the system currently in use in this facility is underrated, and needs to be upgraded by increasing its capacity from 1,500 CFM to 5,000 CFM, an increase of 3,500 CFM.

The above described engineering modifications would increase the capacity by 3.33 times the current volume. Therefore, it is reasonable to predict that the modified system will reduce prevailing exposure levels by the same factor. That is, technologically feasible controls would result in reducing MC concentration from the current prevailing exposure level of 70 ppm to 21 ppm. This reduction in workers' exposure is the product of implementing simple engineering modifications required to upgrade the system so that the minimum design criteria can be met.

Further reduction could be achieved through implementing other

modifications as well as employing appropriate work practices as discussed below. For example, the open face cans contribute significantly to workers' exposure. Cans could be designed in a manner, such that, they are connected to the table, so that the vapors that come off are directed up into the trough where the exhaust slot will capture them. Further, cans should be capped off while they are not in use. An alternative exposure control method would be to provide a turntable to be mounted inside the stripping tank, where furniture pieces can be placed on the turntable and rotated. The turntable inside the stripping tank will allow operators to maintain their position at a fixed location. This approach will facilitate providing a fresh air supply at the workers' fixed location. Providing an exhausted grated floor upon which workers can be stationed, when performing their tasks, would further contribute to achieving the desired reduction in workers' exposure.

*b. Hand stripping.* Although the majority of the work is performed using the flow-on system, hand stripping may become necessary for specific pieces of furniture having complex details that render the earlier method ineffective. In the hand stripping, the stripping fluid is applied with a brush and allowed to penetrate for a while. The loosened paint coat is scraped off using a wire brush or putty knife. The waste material removed, including the stripper, is then placed into another can to be disposed of later. The stripping fluid is only applied to small areas at a time. While the stripping fluid is penetrating one area, the operator begins coating a second area. Once this second area is coated, the first area is then scraped. Care is taken not to be leaning over the area of first coverage while covering the second area.

This operation takes place in the same room as the flow-on system, and occasionally just outside of the room. At the site visited by OSHA, there was no ventilation available for this operation. A typical operation will take anywhere from 45 minutes to an hour. Hand stripping consumes approximately 33.3 gallons/year (Ex. 7-231). Assuming a homogeneous daily consumption, the maximum evaporative loss of MC is 0.017 gallon/hour. This is equivalent to 18.9 liters/hour<sup>4</sup> of MC vapors. This volume of MC vapors generated in a 24 x 30 x 9 ft work room<sup>5</sup> will result in approximately 20 ppm, if 5 air changes per hour are provided. This technological feasibility determination is based on using dilution ventilation which is known to be the least effective

control system. This dilution ventilation system would require only one fan having a capacity of 550 CFM.

*c. Dip tanks.* The dip tank system is commonly used for stripping old paint from metal parts. Although MC is the dominant paint stripping media currently in use, there are several substitutes available, all of which have the same effectiveness as MC. Examples of these substitutes are methanol, acetone, and toluene. Even with the effectiveness and low volatility of these substitutes, their use is not common and is undesirable because of their high flammability rate. Most dipping tanks are not provided with proper ventilation systems. Control of workers' exposure is limited only to providing hinged covers for the tank to confine the vapors during blistering of the paint.

Exposure data indicating the extent and magnitude of the problem are not extensive. However, available information indicates that a typical dipping tank having dimensions of 10 x 4 x 4 ft. is located in a 30 x 40 x 15 ft room (500 m<sup>3</sup>). Depending on the type of objects being stripped and the "stubbornness" of the paint layers desired to be removed, an average of 5 gallons is lost through evaporation daily (per 8 hour shift). This volume of MC loss indicates that the use of dilution ventilation would not be a technologically feasible means of control for workers' exposure. The infeasibility of dilution ventilation is due to the need for an extremely high volume of air. The 682 liters/hour of MC vapors released in a 500 m<sup>3</sup> room with 15 air changes will result in a final concentration of 90.9 ppm. In order to achieve a level of 25 ppm, approximately 60 air changes per hour will be required. Therefore, it is evident from the above calculation, that local exhaust ventilation should be regarded as the preferred control method. Further, the efficiency of the local exhaust method could be substantially increased by implementing minor modifications such as electrical switches. Electrical switches can be used to activate the exhaust system whenever the tank covers are removed. The design of this system is more efficient since operators are not stationed in the vicinity of the dipping tank all of the time. Also, during the blistering duration, the hinged covers are kept closed, hence there is no need to operate the exhaust system.

## 2. Conclusion

Engineering modifications to current control systems are technologically feasible for all of the three types of paint stripping operations. The technological



feasibility of implementing engineering controls to reduce workers' exposure from the current standard to the proposed level of 25 ppm is further demonstrated by increasing the capacity of an existing exhaust system, and implementing modifications to work practices and equipment layout. These modifications in engineering and work practice controls, and equipment layout resulted in lowering workers' exposure to MC from 340-1726 ppm (average 812 ppm) to 22-35 ppm (8 hr. TWA averages 18 ppm). At one furniture stripping facility, the feasibility of achieving the proposed 25 ppm through engineering and work practice controls was further emphasized by the statement, " \* \* \* exposures can be further reduced by improving the design of the rinse area and by limiting the workers' access to the drum containing the stripping solution (Ex. 7-247).

#### H. Degreasing and Metal Cleaning

Exposures from vapor degreasing originate from vapors rising past condensation coils (most likely due to underrated capacities of condensation coils). The vapors are emitted from parts that may contain liquid MC in, or on them, upon removal from the degreasing tank (trapped condensed vapors), from spraying liquid MC onto parts with a spray lance (splattering), from leakage of pipes and pumps that carry the solvent, during cleaning of tanks, and/or from implementing improper techniques and work practices.

Workers' exposures could be controlled through the implementation of the following technologically feasible engineering and work practice controls. Local exhaust is the primary engineering control for reducing exposures to MC vapors. Depending on the size of the tank and its associated exposed area of the liquid MC, either of two types of slotted hoods can be used. The first is the one sided slotted hood and the second is a multiple sided (including full perimeter) slotted hood. Either of these two types of hoods should be provided with make up air in the form of a sweeping apron or push pull system, so that the exhaust efficiency of the system can be maximized and maintained throughout the operational duration. Design criteria for these types of control systems are readily available, and their implementation has proven to be effective for the reduction of workers' exposure to MC.

#### 1. Engineering Controls

a. *Mechanical ventilation.* The ventilation system observed on an open top vapor degreaser, at the facility visited by OSHA, was a down draft

system with a slotted hood, located around the perimeter of the tank. The degreasing tank has dimensions of 10' x 5' x 12' (length x width x depth) and was equipped with a slotted hood having a 13,000 CFM design capacity (Ex. 7-233).

Evaluating the current capacity of the system indicates that the system is underrated by a factor of 2.85.<sup>6</sup> The prevailing exposure level of approximately 80 ppm reveals that engineering modifications to the system to meet the proper design criteria are expected to reduce these prevailing levels proportionally (i.e. reduce exposure levels to 28 ppm).<sup>7</sup> The appropriate design criteria that yields a system capacity of 37,000 CFM is based on the assumption that all system components (e.g. condensation coils and refrigerated free board) are designed, rated, and functioning properly.

b. *Condensation and refrigerated freeboard coils.* Condensation coils are the most important component on a vapor degreaser. When coils are properly functioning, they confine MC vapors below the freeboard by condensing hot vapors on their cool surfaces. Further reduction in emissions can be achieved when a refrigerated coil is attached at the freeboard above the condensation coils. These devices assist in reducing solvent loss and workers' exposure, and are not meant to be used alone to control the vapor level, but in conjunction with condensation coils to help reduce the vapor release into the work environment (Ex. 7-234). Using only condensation coils, resulted in exposures ranging from 179 to 219 ppm (Ex. 7-233).

With a refrigerated coil attached to the freeboard, the MC concentration was lowered by 55%, yielding exposure levels ranging from 60 to 100 ppm. The cooling water temperature of this system was not properly conditioned, (i.e. inlet and outlet water temperatures were 68°F and 100°F, respectively). Further reduction in exposure levels can be achieved through lowering the cooling water temperature (Ex. 7-233).

One of the major problems responsible for the excessive workers' exposure is the lack of the understanding of the chemical and physical characteristics of MC. When water at ambient temperature (68°F) enters condensing coils and then exits at 100°F, (nearly the boiling temperature of the solvent), the condensation efficiency of the coils will be extremely reduced, and consequently high levels of exposures will prevail. Simple extrapolation, considering the MC vapor pressure at 100°F, indicates that by

feeding a chilled fluid (e.g. brine or water and glycol mix) at 20°F and exiting at 60°F, the relative vapor pressure of MC would decrease by 67%<sup>8</sup>, yielding an exposure level of approximately 26 ppm. That is, incorporation of this technologically feasible modification, without upgrading the mechanical exhaust system previously discussed, will result in reducing the current prevailing exposure of 80 ppm to 26 ppm. When combined engineering modifications, (i.e. upgrading the exhaust system capacity and implementing the chilled water system), are incorporated, the prevailing exposure level will be reduced to approximately 9.1 ppm  $((80 \times 0.325) / 2.85)$ .

The above indicated feasible reduction in exposure levels (i.e. through modifications to the exhaust system, incorporating a refrigerated coil, and using a chilled solution in the condensation coil), can only be maintained if an appropriate preventive maintenance program and work practices are properly implemented.

c. *Maintenance.* Preventive maintenance is critical for efficient operation of exhaust systems. The system should be checked regularly for proper operation of the fan (e.g. belt tension, direction of blade rotation, unbalanced blades \* \* \* etc.). Loose belts on drive systems can cause extreme reduction in fan speed, which consequently results in decreasing the volume of exhaust air, as well as wear and tear on both the fan and the motor. Proper functioning of fans can be checked through measuring slot velocities against the design criteria. Further, checking and repairing leaks, collapsed piping, and blockage are the main components of good maintenance practices which are essential for reduction of workers' exposure.

#### 2. Work Practices

If automatic nozzles are not available and manually operated spray lances are used, spraying should be performed below the vapor level. Spraying above the vapor level will cause turbulence and will result in excessive exposure in the work area. If the pressure on spray nozzles is not properly adjusted and maintained to provide adequate rinsing action, splattering and consequently excessive and unnecessary exposure will result. Overloading baskets in open top vapor degreasers should be prohibited. The basket which enters the tank with the parts should be carefully lowered, so that the basket does not act like a piston which will force MC vapors out. Workers should be trained to



arrange the parts appropriately, so that vapors are not trapped in and between parts. If this is not possible due to the shape of the parts, then drain holes, instead of the tilting practice, should be incorporated in the design of the parts to allow any liquid MC to drain off before the removal of the basket from the tank. If tilting is necessary, it should be done below the vapor level. The speed of raising and lowering of the basket should not exceed 11 ft/min (Ex. 7-234).

### 3. Alternative and Supplemental Control Measures

*a. Isolation.* Isolation is a technologically feasible approach for the control of workers' exposure. The use of a monorail degreaser lends itself to the desired isolation and achieves significant reduction of workers' exposure. In this system, parts are carried in and out by conveyor hooks through small openings in the wall of the building. The employees load and unload parts onto the hooks approximately 15 to 20 feet away from the degreaser. To demonstrate the effectiveness of this isolation approach, a vapor degreaser that uses water at ambient temperature in the condensation coils (from the same source as the open top batch vapor degreaser previously discussed), coupled with a refrigerated coil device results in workers' exposure in the range of 10 to 11 ppm. That is, the simple isolation of the degreaser resulted in low exposures without the aid of any mechanical ventilation system. Exhaust systems are necessary to provide workers with protection during periods of time spent in the degreasing room for the removal of parts that have fallen off the hooks, emergency situations, or during the cleaning and maintenance of the degreaser (Ex. 7-233).

*b. Vapor confinement.* The biggest problem for the exhaust system is the disturbance of air from in and around the tank. To help eliminate poor capture efficiency due to disturbances of the air flow pattern, an enclosure could be designed for the open top vapor degreaser. A canopy with a telescopic or flexible duct can be attached to the chain hoist that lowers the basket of parts into the tank. When the basket is lowered into the tank, the canopy will be lowered simultaneously, such that, when the basket is in the tank the canopy will cover the tank, hence preventing vapors from escaping to the workers' breathing zone. The canopy can be made of a clear material allowing operators to observe the basket in the tank. Glove ports can be attached to the canopy, so that operators will be able to insert their hands through the canopy

into MC-resistant rubber gloves, to facilitate rinsing the parts with the spray lance. The canopy will not only reduce workers' exposure through the confinement of MC vapors within the tank, but will also reduce exposure of workers who are stationed in the vicinity of the tank. It should be noted that sufficient clearance between the canopy and the tank should be maintained to allow for air to enter the exhaust system, otherwise excessive negative pressure will develop and render the exhaust system ineffective. This canopy will also keep operators from leaning into the tank unnecessarily and exposing themselves unnecessarily to excessive MC concentrations.

### 4. Substitution

Aqueous cleaning as a substitute process is currently available and in use in some facilities. However, there are some limitations on the degree of the parts' cleanliness which affects the acceptance of their subsequent processing (e.g. painting, soldering, welding). Research is in progress to develop a detergent that will sufficiently clean parts for painting. However, environmental consideration for water purification deserves special attention. Although aqueous cleaning may not be suitable/proper for all types of degreasing, it is technologically feasible for various degreasing operations, such as printed circuit boards (Ex. 7-233).

### 5. Conclusion

A feasible engineering modification of the current capacity of the exhaust system has been demonstrated to result in extensive exposure reductions. Supplemental engineering controls (i.e. using a refrigerated coil and chilled solution) have been demonstrated to result in further reduction of exposure levels. The combined modifications would yield approximately 90% reduction in the current exposure levels (from 80 ppm to 9 ppm). Further, appropriate work practice controls and implementation of preventive maintenance should be incorporated as an integral part of the feasible control measures, so that the system's effectiveness can be maintained.

#### *1. Cellulose Triacetate Fiber and Film Base Production.*

##### *1. Cellulose Triacetate Fiber.*

The technological feasibility assessment is limited to controls applicable to the manufacturing of cellulose triacetate film base. Since only one manufacturer of triacetate fibers currently uses MC, OSHA regards this as evidence of the feasibility of MC

substitution in this industrial application. Therefore, no engineering determination is needed since other producers have successfully converted their production processes to be compatible with the substitute.

##### *2. Cellulose Triacetate Photographic Film Base*

*a. Production processes and exposure levels.* Methylene Chloride (MC) is used as a solvent to dissolve cellulose triacetate pellets for making photographic film base. MC is used because of its low flammability as well as its low order of chemical reactivity and fast evaporation rate. There are two main processes in the making of the cellulose triacetate film base. These processes are dope preparation and roll coating (Ex. 7-235).

*i. Dope preparation.* MC is used to dissolve the cellulose triacetate pellets. The solution is conditioned with plasticizers and other solvents to produce the dope. Impurities in the dope are removed by several successive filtration processes (i.e. continuous screen filter, continuous wash press, transfer and multipress filters). The dissolution of the triacetate pellets and the successive filtration processes are carried out in a closed system. The filtered dope contains 60% to 65% MC by weight (Ex. 7-235).

Workers' exposure during dope production occurs during preparation of crude dope (dissolving cellulose triacetate pellets in MC), dressing filters (changing), unscheduled/scheduled maintenance and leaks from pumps and transfer lines. Exposure levels measured during crude (unfiltered) dope preparation ranged from 6 to 75 ppm (geometric means) with 38% of the samples below 25 ppm (Ex. 7-235).

The filtration process starts by passing the freshly prepared crude dope through a continuous screen filter. The cleaning of the screen is performed through reverse flow or back flushing. The flushing solvent which carries the coarse contaminants (that are being released from the screen during the back flushing cycle), is pumped to the solvent recovery operation. The continuous screen filter is a permanent and sealed filter and therefore, its contribution to workers' exposure is very limited (Ex. 7-235).

The dope, after passing through the continuous screen filter, to remove fiber contaminants, is piped to the continuous wash press filter. The wash press filter consists of a cartridge frame holding the filter plates on which the filter pads are mounted. The total wash press filter assembly (cartridge frame, filter



mounting plates and filter pads) are housed in a cylindrical filter shell (Ex. 7-235).

Workers' exposures to MC occur during the dressing of the wash press filter (removing the old filter pads from the plates and replacing them with new pads). There are three tasks performed during filter dressing which result in MC vapor release and contribute to workers' exposure. Currently, these tasks are performed without purging the filter housing, hence all confined MC vapors are released to the work environment. The first task is unbolting and removing the cover of the cylindrical filter shell/housing. The second task is lifting out the MC saturated filter cartridge from the filter shell with a hoist, and allowing the excess MC liquid to drip. This is the most serious source of workers' exposure, since there are no controls in place to confine the MC drippings and their associated vapor release. The third task is the removal of the old filter pads from the mounting plates. Workers' exposures occur as the result of MC evaporation from the wet pads. Removal of the old pads must be performed while the pads are still wet, because if dried, the pads will adhere to the mounting plates and their removal will be difficult and time consuming. The combined exposure level that prevails as a result of performing the continuous wash press filter dressing is 160 ppm (geometric mean).

The filtered dope from the continuous wash press filter undergoes two additional stages of purification, transfer and multipress filtration. Although there are some variations in the size, configuration, methods of disassembling, assembling and compressing the filter pad as well as the purpose of the filtration process, sources of workers' exposure during the performance of these tasks are similar to those described above (i.e. continuous wash press filter dressing). Exposures measured during changing the transfer filters and multipress filters were 200 and 120 ppm (geometric mean values), respectively (Ex. 7-235).

*ii. Roll coating.* Workers' exposures to MC vapors in the roll coating process occur at two operations, the casting of the film base and solvent recovery operation.

*(A) Casting of film base.* In the film base casting operation, the filtered dope is piped to the receiving hopper of the coating machine. The dope is then spread across a rotating polished metal wheel. As the coating wheel rotates, MC and other solvents are evaporated from the dope inside the casting machine enclosure. At the completion of one turn, the formed film base is stripped off the

wheel and conveyed through the curing station for further solvent evaporation by hot recycled air with a temperature of 121-138 °C. The cured film base is wound onto a core and is moved to another section for inspection, packaging and further processing to produce photographic products. The roll coating process is housed in an enclosure maintained under a slightly positive pressure to prevent contaminant intrusion into the machine housing (Ex. 7-235).

The major source of employee exposure to MC vapors in the roll coating operation is the evaporation of MC inside the coating machine enclosure, and the subsequent MC vapor release when access doors and windows are opened during routine maintenance (scheduled/unscheduled and product rescue activities). The maintenance activities include wheel and dope hopper cleaning and trouble shooting. The rescue activities include tie-on sheets to the threading strap, trimming edge and performing other miscellaneous adjustments. These activities are performed through access doors and windows. Workers' exposure occurs as a result of MC vapor release from the machine enclosure which is maintained under positive pressure (Ex. 7-235).

*(B) Solvent recovery.* In the solvent recovery operation, vapors of MC and other solvents are recovered (condensed and purified) for reuse in the dope preparation (dissolving cellulose triacetate pellets). The evaporated solvents are ducted from the film casting machine enclosure to the heat exchanger in the solvent recovery section by two air handling systems. These are housed in the film base casting section. The condensed solvents are purified by distillation. The effluent containing the uncondensed MC (about 3% of the total consumption) is withdrawn from this recovery section, and returned to the film base casting machine enclosure for the purpose of maintaining the desired positive pressure inside the film casting enclosure (Ex. 7-235).

Employee exposure in the solvent recovery section is caused by leaks of the effluent containing uncondensed MC. The combined effects of MC release in both the casting of film base and the solvent recovery result in exposures from 20-50 ppm with 63% of the samples being below 25 ppm (Ex. 7-235).

*b. Engineering controls.* Current control strategies for reducing workers' exposure include machine and enclosure retrofit, upgrading ventilation systems to direct solvent vapors away from the workers' breathing zones and to provide

fresh makeup air, providing permanent or portable local exhaust systems during the performance of high exposure tasks (e.g. filter dressing and maintenance activities), and upgrading solvent recovery capacity to reduce the release of uncondensed MC vapors. Air-supplied respirators are used to reduce peak exposure during filter dressing operations. Since current engineering controls do not sufficiently reduce workers' exposure to MC vapors, the dressing of the transfer filter occurs in a nearby enclosed dressing station. This station is equipped with a temperature controlled air supply and exhaust system, which directs the air flow downward and away from workers' breathing zones. The dressing of multipress filters is done on a movable table equipped with a local exhaust system. Employees are required to use air-supplied respirators for additional protection while handling spent filter pads. At the completion of filter dressing, spent filter pads are placed in fiber drums for incineration (Ex. 7-235).

Most maintenance activities involve exposure to the process equipment, often in hard to reach spaces, where conventional exhaust systems would not fit. A portable ventilation unit was designed and placed in service in the production building. Table 3 summarized the engineering controls and protective equipment used in dressing operations (Ex. 7-235).

TABLE 3.—ENGINEERING CONTROLS & PROTECTIVE EQUIPMENT

Dressing operations	Engineering controls and protective equipment
Continuous and Wash Press Filters.	Portable 5,000 CFM ventilation; operation performed outside; cartridge respirator available but their use is not mandatory.
Transfer Filters...	5,000 CFM down draft ventilation at work area; air-supplied respirator worn at worker discretion.
Multipress Filters.	6,000 CFM down draft ventilation at work bench; air-supplied respirators are available for some tasks.

*i. Leaks from transfer lines, pumps and air-MC effluent conduits.* Control of workers' exposures that result from leaks from transfer lines, pumps and air-MC effluent conduits can feasibly be achieved through several means. Replacement of seal-pumps with magnetic drive pumps will result in substantial reduction of repair frequency and most likely elimination of leaks. Leaks from seams (connected joints) in air-MC effluent conduits can be feasibly eliminated, or at least reduced by welding the joints or sealing



the leak sources using plastic-silicon caulking. Further reduction in exposure levels due to leaks can be feasibly achieved through early leak detection. Helium leak detection devices are available and can be used to determine the amount and the source of leakage.

*ii. Dope production, dressing of filters—(A) Use of Mobile Confinement Canisters.* Currently, the filter dressing is performed in the field without appropriate purging of the filter canister/housing before its opening. Decreasing the time during which the top of the filter canister remains open will also result in substantial reduction of workers' exposure. In order to reduce the amount of MC vapor released during filter changing, the filter canister should be purged with air or an inert gas. The purged effluent should be directed or ducted to the MC recovery system. Providing a half circle exhaust slot, connected to the exhaust blower by a means of a flexible hose, will enable the worker to unbolt the filter canister top under controlled conditions. Design criteria for determining the exhaust system capacity are available, and have proven to be effective for controlling emission or vapor release from similar operations.

The current technique of lifting the spent filter cartridge and allowing it to drip in the work area, and replacing the filter pads at the site, should be discontinued. Workers' exposure resulting from performing these tasks can be controlled through confining the MC emission in a portable filter canister that can be mounted on casters for easy mobility. Upon lifting the spent filter cartridge, it can be set or placed inside the portable canisters, and the canister top can immediately be positioned to cover or confine any MC vapors that can be potentially released into the work environment. During the replacement of the spent filter pads, the use of a preassembled filter cartridge, to be inserted in the filter shell would eliminate the need for the workers to perform their duties in an uncontrolled field environment. This would only require the purchase of a spare filter frame and filter plates. The mounting of the fresh filter pads on the spare filter plates, and assembling them on the filter frame can be safely performed in "an office like" environment with no need for control systems, since the potential for exposure to MC is non-existent.

The removal of the spent dry filter pads from the mounting plates can be feasibly achieved, without subjecting the workers to unnecessary exposure, through one of two means (dry and wet method). In the dry method, the dry filter

pads are subjected to a hot air stream to soften and loosen the filter pads for their easy removal. If the hot air stream method is proven to be ineffective to loosen the dry spent filter pads, the wet method can be used. In this method, MC or preferably other safer solvents can be used to wash out the dry dope from the spent filter pads. The addition of the solvent can be performed in the portable canister which already houses the spent filter cartridge. Further, the portable canister would be provided with feed and discharge ports, so that the wash-out solvent can be pumped, (under closed system conditions), to the distillation operation for recovery. In this case, a waste drum equipped with self-closing covers, would be needed to confine the release of solvent vapors from the spent filter pads which are removed from the mounting plates. Purging the mobile canister with an inert gas/air, after completing the pumping of the wash-out solvent, must be performed before opening the canister for removing the spent filter pads. No information on the possibility of using a disposable filter cartridge assembly is currently available.

*(B) Modification to the filter dressing room.* Technologically feasible modifications to the design of the exhaust and makeup air systems of the filter dressing room can also achieve the desired reduction of exposure levels. If the dressing room is provided with an exhaust system in the form of a grated floor, and makeup air slots are distributed uniformly and in a manner that maintains a vertical direction of air, then the released vapor will be exhausted at the floor level, while a continuous fresh air flow will be available at the workers' breathing zone.

The current available exhaust system of 5,300 CFM is sufficient to provide 166 air changes per hour (dressing room volume  $12 \times 20 \times 8$  ft). However, because of the inefficiency of the fresh air supply distribution, the inability to maintain the shortest distance to the exhaust slot, and the ineffectiveness of maintaining high velocity make-up air to overcome or force the MC vapors downward, the current workers' exposure levels are excessive, and need to be reduced through the implementation of the above indicated technologically feasible control approaches.

Assuming an evaporation loss of 2 gallons, or approximately 15 pounds per hour, when filter dressing is performed, and assuming that the available 5,300 CFM function is dilution ventilation, (which the least efficient control

system), prevailing exposure levels would be approximately 288 ppm.<sup>9</sup> It should be noted that this concentration results from homogeneous dilution which is unrealistic. In other words, there is a likelihood that the concentration at workers' breathing zones exceeds the calculated 288 ppm level.

A downdraft exhaust system with an overhead high velocity of fresh makeup air yields a minimum efficiency rate of approximately 20 times that of dilution ventilation. Therefore, the current available 5,300 CFM would be sufficient to reduce the MC concentration to approximately 15 ppm when the above modifications are implemented properly. If the actual evaporation loss of MC exceeds the above assumed 2 gallons or 15 pounds per hour, then the exhaust system should be proportionally rated. For example, if the actual evaporation loss is 4 gallons or 30 pounds per hour, the exhaust system capacity should be rated at 10,600 CFM.

The selection of any of the above mentioned technologically feasible control methods depends on the frequency and duration of the filter dressing, the size and configuration of the filter cartridge, and the type of equipment used to complete the filter dressing task. Further, certain modifications to the grated exhaust floor may become necessary. If this design is used for dressing tasks, and the possibility of releasing liquid MC (that is trapped between the plates) exists, a drip pan placed below the grated floor (receiving container) equipped with an elbow trap (smallest diameter possible) should be incorporated in the system design. The elbow trap is necessary to limit the surface area from which liquid MC may be lost through evaporation.

*iii. Roll coating—(A) Film base casting.* Exposure to MC in the film base casting operation result from MC vapor releases during the opening of access windows and doors of the casting machine, for the purpose of performing repairs. As indicated previously, the casting equipment are housed in an enclosure that is maintained under positive pressure to prevent contaminant intrusion. Therefore, when access windows and doors are opened to perform maintenance and rescue tasks, workers are exposed to excessive MC levels.

The technological feasibility assessment of engineering controls for this operation is based on assuming a worst case scenario. Since the total consumption of MC is rated at  $200 \times 10^6$  pounds per year (Ex. 7-146), and the recovery efficiency is currently rated at



97%, it would be reasonable to quantify the MC loss to about  $6 \times 10^6$  pounds per year.

The worst case scenario assumes that all unrecovered MC, (6,000,000 pounds per year), escapes to the work environment surrounding the film casting equipment. Under this assumption, the exposure level in the work environment that surrounds the film casting equipment is not expected to exceed 118 ppm.<sup>10</sup> Since the prevailing exposure levels range from 20 to 50 ppm, an average of 35 ppm, it would be reasonable to assume that approximately 70% of the 6,000,000 pounds of unrecovered MC is lost to the outdoors environment, and only 30% of the 6,000,000 pounds escapes to the work environment.

The 30% of unrecovered MC that escapes to the work environment during the performance of routine maintenance and through gasket leaks around access doors and windows, can be quantified as 3.42 lb/min<sup>11</sup>. This amount of MC loss yields approximately 16.00 ft<sup>3</sup> min<sup>-1</sup><sup>12</sup> of MC vapor. Therefore, dilution ventilation cannot be regarded as a realistic engineering approach for achieving the desired reduction of workers' exposure, when maintenance through the access doors is performed. Three viable options to achieve the needed reduction of workers' exposure are described below.

The first option is to erect a partition along the access doors and windows so that air locks are generated, hence confining MC vapors within air locks. Providing air locks will not only facilitate the installation of an efficient exhaust system for the access doors and windows, but will also reduce the diffusion and escape of MC vapors to the surrounding work environment. Currently, workers who are not directly involved in performing the maintenance or rescue tasks are unnecessarily exposed to fugitive MC concentrations ranging from 20 to 50 ppm. A portable local exhaust system with fresh make-up air, being supplied at a sufficient high velocity to overcome the thermal rise of effluent containing MC vapors, will result in redirecting the MC effluent vapor downward, and/or away from the breathing zone of the operators. Exhaust slots are to be incorporated along the perimeter of the film casting enclosure inside the confinement of the air lock. A properly rated portable exhaust blower, provided with a filter to eliminate potential contaminants from entrainment inside the casting enclosure, is expected to provide the needed protection for the workforce

without resorting to the use of air supplied respirators.

The number of portable exhaust systems should be compatible with the maximum number of access doors/windows that are to be potentially opened at any one time. That is, if a maximum of 5 access windows/doors are expected to be the maximum number to be opened for performing the required maintenance work, a maximum of 5 portable exhaust blowers must be available at the work site.

The second option is to design a portable enclosure mounted on casters and provided with an independent and recyclable fresh air supply. The recyclable fresh air supply requires equipping the enclosure with a carbon adsorption bed, or other similar media. This will remove MC from the exhaust effluent before its recirculation as a fresh air supply. An alternative to providing a carbon adsorption bed is to provide feed ports in the casting enclosure, so that the fresh air supply can be continuously exhausted from the portable enclosure and fed into the casting enclosure. The portable enclosure can be rolled from one location to another, in accordance to the work demand. The advantage of this approach is to overcome any space limitation that may occur if a partition is set up to create an air lock.

The third option is to increase the capacity of the air handling units that duct the air-MC effluent to the solvent recovery system. Increasing the capacity of the air handling units will result in maintaining the casting machine's enclosure under negative pressure, hence the escape of MC vapors through the access doors/windows will be eliminated. There are concerns regarding potential contamination of the environment inside the casting enclosure. If the enclosure is maintained under negative pressure, a portable enclosure similar to that described under the second option should be designed. If this enclosure is equipped with a filtered make-up air supply, then the concerns of contamination will be eliminated. One of the advantages of this approach (i.e. maintaining the casting enclosure under a slight negative pressure) is that there will be no need for any additional modifications (e.g., the need to retrofit the doors and windows with new latches and to replace the leaking gaskets).

(B) *Solvent recovery.* Improving the chilling capacity of the system is expected to result in a better recovery rate of MC and hence reduce the MC concentration in the recycled effluent. Further, the air-MC effluent leaking from

the access windows/door would contain a lower concentration of MC. This would be of significant importance if the enclosure of the casting operation is maintained under positive pressure.

c. *Conclusion.* Reduction of workers' exposure could be achieved through a variety of alternative engineering controls. Providing a spare filter assembly frame and a mobile filter canister to house the spent filters would contribute significantly to the reduction of workers' exposure during filter dressing. Further, modifying the floor of the current filter dressing room to accommodate a grated exhaust system, and providing high velocity overhead make-up air is expected to significantly reduce workers' exposure. Increasing the capacity of the chilling system in the solvent recovery operation would result in decreasing the MC concentration in the return air-MC effluent. Further, air-MC effluent escaping from access windows and door gaskets would be significantly reduced if the casting machine housing is maintained under slightly negative pressure.

#### J. Electronics

In assessing the use of MC in the electronics industry, OSHA determined that MC application in this sector is closely allied to that in cold degreasing. Engineering controls previously described in degreasing operations are applicable for this industrial application. Therefore, OSHA determined that there is no need for repeating the technological feasibility assessment described in the degreasing section.

#### K. Miscellaneous Uses

##### 1. Food Extraction

In the past, as indicated in Section IV, MC was used in a variety of food extraction processes. These processes included decaffeination of coffee, extraction of hops and manufacture of oleoresins. However, information from the trade association (HSIA) indicates that MC is no longer being used for these purposes. Specifically, the largest use, decaffeination of coffee beans, has been voluntarily discontinued. Therefore, OSHA determined that there was no need to conduct an engineering feasibility assessment for this industrial use. OSHA is seeking information on any current uses of MC in food extraction.

##### 2. Pesticide Formulation

Current information indicates that in response to an EPA mandatory call-in announcement, no pesticide user/formulator has reported the use of MC in pesticides. Accordingly, OSHA believes



that MC usage in pesticides either has already been, or soon will be phased out. However, there is an indication that MC is currently used during the process of manufacturing pesticides, (e.g. for ancillary purposes other than formulations). Therefore, OSHA solicits public comment on the extent, if any, to which MC is used in the process of manufacturing pesticides.

### 3. Solvent Recovery

The technological feasibility of achieving the new proposed PEL has been described in detail in the section of solvent recovery (cellulose triacetate). OSHA determined that similar engineering control methods are applicable to this industrial sector, and therefore, there is no need for its repetition. OSHA acknowledges that minor modifications may be required. However, the same engineering design criteria would be employed.

### 4. Ink Manufacture

In the past, as indicated in section IV, MC was used in ink manufacture. However, current information indicates that due to health concerns regarding MC usage, ink manufacturers are no longer using MC in their formulations. In this regard, OSHA believes that ink manufacturers have already substituted away from MC, and it is no longer being considered as a critical solvent in this industrial segment.

Since the solvency properties of MC are no longer regarded as essential by ink manufacturers, OSHA believes that substitutes are also available for MC use in blanket wash (cleaning of the printing plates). However, there is an indication that MC is still being used by some printing industry for blanket wash. OSHA is requesting comments on the extent and the magnitude of current usage, if any, in blanket wash.

### Footnotes

<sup>1</sup> 200 g/s × 60 s/min × 60 min/hr × 0.29 cal/g°C × 33.34 T°C/(251.996 cal/BTU)

<sup>2</sup> When all samples are considered (i.e. non-detectable and outliers included) the current average concentration of 23.56 ppm will be reduced to less than 6 ppm upon the incorporation of chilling coil within the engineering controls.

<sup>3</sup> One method is the measuring of exposures by using a 3M-3500 organic vapor monitor. The second method is the measuring of exposures using the current NIOSH method of the 150 mg charcoal tube. Samples collected in charcoal tubes are more reliable since they are processed and analyzed in an on-site laboratory. This method produces reliable data since there is no need for implementing any sampling preservation procedure before analysis (Ex. 7-216).

<sup>4</sup> [70.4 lb/hr × 456 g/lb × 24.45 L/mol × 10<sup>6</sup> ppm]/[84.5 g/mol × 60 min/hr × 28.37 L/ft<sup>3</sup> × 1150 ft<sup>3</sup>/min × 5 pans].

<sup>5</sup> 33.3 gal/yr × .80 MC × yr/250 days × day/8 hr × 128 oz/gal × 29.5 cc/oz × 1.3g/cc × 24.5 L/mol × mol/85 g = 18.4 L/hr.

<sup>6</sup> Furniture stripping occurs in a room that is 24' × 30' × 9', isolated from the general working area of the 90' × 108' × 18' building, but sharing a common air space due to the lack of a roof. The concentration of MC (fugitive) in the general area is approximately 10 ppm (Ex. 7-231). If the paint stripping room where furniture is stripped is fully partitioned by providing a ceiling, this unnecessary workers' exposure in the general surrounding area would be eliminated.

<sup>7</sup> Q(1)/Q(2) = (3.7 × 5 ft.) × (200 fpm) × (5 × 2 ft.)/13,000 = 37,000/13,000 = 2.85.

<sup>8</sup> 80 ppm/2.85 = 28 ppm.

<sup>9</sup> C<sub>2</sub> = VP<sub>2</sub>(out) - VP<sub>2</sub>(in)/

VP<sub>1</sub>(out) - VP<sub>1</sub>(in) × C<sub>1</sub>.

C<sub>2</sub> = VP(60°F) - VP(20°F)/

VP(100°F) - VP(68°F) × [80

ppm] = 0.325 × 80 = 26.4 ppm.

<sup>10</sup> 15 lb/hr × 456 g/lb × 24.5 L/

MW × 10<sup>6</sup> × 1.3 g/cc/28.37 L/ft<sup>3</sup> × 84 g/

MW × 5,300 cu ft/min × 60 min/hr = 288 ppm.

<sup>11</sup> 6,000,000 lb/yr × 456 g/lb × 24.5 L/mol × vol/yr/365 d × 10<sup>6</sup> ppm/24 hr/d × 60 min/hr × 450,000 ft<sup>3</sup>/m × 84.5 g/mol × 28.37 L/ft<sup>3</sup> = 118 ppm.

<sup>12</sup> 6,000,000 lb/yr × 30%/365 d/yr × 24 hr/d × 60 min/hr = 3.42 lb/min.

<sup>13</sup> 3.42 lb/min × 456 g/lb × 24.45 L/mol/84.5 g/mol × 28.37 L/ft<sup>3</sup> = 16 ft<sup>3</sup>/min.

## VII. Health Effects

### A. Introduction

Until the rodent studies conducted by the National Toxicology Program (NTP), the Dow Chemical Company and the National Coffee Association were completed, little was known about the adverse health effects potentially associated with chronic exposure to MC. Health-based standards recommendations were based on prevention of irritation and injury to the neurological system.

The rodent bioassays now indicate that MC is carcinogenic to rats and mice. Based on two epidemiologic studies, OSHA preliminarily concludes that there is suggestive evidence of increased cancer risks in MC-related worker populations. The epidemiological evidence is consistent with findings of excess cancer in the experimental animal studies. OSHA concludes from these data that MC is a suspect or probable human carcinogen. NIOSH has reached a similar conclusion and regards MC as a potential occupational carcinogen. The International Agency for Research on Cancer (IARC) has classified MC as an animal carcinogen.

Much research has also been conducted on the metabolism and toxicity of MC in recent years. Although the current exposure limits were set to

prevent neurological damage, recent research findings suggest that MC can be toxic to the central nervous system (CNS) at concentrations much lower than previously suspected. Research on metabolism of MC has identified CO as a human metabolite of MC, leading to consideration of the toxic effects of CO on the heart and CNS. In addition, OSHA will evaluate indications that MC and CO interact synergistically (Exs. 7-182, 7-175), and will consider if it is necessary to address combined exposure through this rulemaking.

### B. Disposition and metabolism of MC

#### 1. Absorption and Distribution of MC

MC vaporizes readily at room temperature and is well absorbed through the lipid barriers of cell membranes in the lungs, intestine and placenta in rats and humans (Exs. 4-5, 7-16). MC has been detected in the kidney (Ex. 7-17), liver and brain (Ex. 7-18). In addition, trace amounts of MC have also been found in body fluids, such as human milk (Ex. 7-16) and the urine of dogs and humans (Exs. 7-14, 7-15). Exposure to MC leads to wide distribution of this compound in the body and, potentially, depending largely on dose, makes MC and its metabolites available for toxic interaction with tissues throughout the body.

Inhalation is the most significant route of entry for MC in occupational settings. The quantity of MC taken into the body depends on inspired air MC concentration, pulmonary ventilation rate, duration of exposure to MC, rates of MC diffusion into blood and tissues and solubility of MC in blood and tissues. The concentration of MC in alveolar air upon initial exposure increases rapidly, approaching the concentration of MC in the inspired air until the concentration of MC in alveolar air is almost equal to that in ambient air. After total body equilibrium is attained during exposure, uptake is balanced by elimination of MC (primarily through the lungs) and metabolism (Exs. 7-15, 7-115).

The uptake and elimination of MC has been well described in human and animal studies (Exs. 7-156, 7-157, 7-174). The solubility of MC in both water and lipid suggests that it distributes with the body water as well as in various tissues. High concentrations of MC have been localized in the adipose tissue of animals and humans. The adipose tissue MC concentration equilibrates very slowly to ambient exposure levels. MC is released very slowly from adipose tissue, providing a continuing dose of MC for metabolism after exposure has



been terminated (Exs. 7-156, 7-158, 7-120).

Dermal absorption of MC is a relatively slow process. In 1964, Stewart et al. (Ex. 7-13) measured the rate of dermal MC absorption in volunteers who immersed a thumb into liquid MC. It was determined that, although MC is lipophilic, the rate of dermal MC absorption is not significant when compared to absorption of MC resulting from inhalation exposure. In order to contribute significantly to body burden of MC by the dermal route of exposure, it would be necessary to immerse the hands and forearms in liquid MC for an extended period of time. Stewart has also reported that contact with liquid MC is accompanied by an intense burning sensation after a few minutes. The pain associated with direct contact and the slow rate of absorption would tend to limit systemic exposure via this route.

The investigation by Stewart et al. looked at the effect of dermal exposure to pure MC solutions. In paint strippers and other MC formulations, thickeners and other agents are generally added to the MC. These agents may influence the rate of dermal MC absorption and evaporation of MC from the skin. An example of this is a paint stripper to which paraffin has been added to retard evaporation of MC from the stripping surface. The paint stripper will not quickly evaporate from the surface of the skin. This prolonged skin contact with MC may cause irritation and skin burns and increased absorption of MC through the skin, leading to increased toxicity at other organ sites.

Absorption of MC through the oral route is rapid and virtually complete. However, this route is not an important source of occupational exposure to MC (Ex. 7-170).

## 2. Metabolism of MC

It has been established by Kubic and Anders (Ex. 7-167) and Ahmed and Anders (Ex. 7-25) that MC is metabolized by rat liver enzymes *in vitro* by two distinct pathways. The first pathway is the mixed function oxidase system (MFO) associated with the microsomal cell fraction and the second is the glutathione dependent pathway localized primarily in the cytoplasm. The MFO pathway yields CO as the final end product. There is some evidence that significant amounts of CO<sub>2</sub> may also be produced in this pathway. The glutathione dependent pathway is mediated by glutathione-S-transferase (GST) and yields CO<sub>2</sub> as the end product and formaldehyde as a metabolic intermediate. Both pathways have the potential to produce reactive intermediates during metabolism which may subsequently interact with cellular constituents such as DNA, RNA, proteins and lipids. The liver is the most active site of MC metabolism by both pathways in all species examined.

Animal data indicates that the MFO pathway is saturated at relatively low levels of exposure (less than 500 ppm), while the GST pathway remains linear throughout the exposure levels examined (Exs. 7-161, 7-171). Saturation of the MFO pathway in humans has been estimated to occur at a level which is within the range of the animal data (estimates range from 200 to 1000 ppm

MC) (7-114, 7-115, 8-32). The GST pathway is not thought to be saturated for any species at any of the doses examined.

The saturation of the MFO pathway has been used as evidence that the carcinogenic metabolite of MC, if one exists, is generated in the GST route of metabolism (Exs. 7-125, 8-32, 14b). This conclusion is supported by the correlation between the carcinogenic response and the increasing level of GST metabolite produced with increasing dose of MC. This association occurs at MC concentrations above which the MFO pathway is believed to be saturated.

## C. Carcinogenicity

### 1. Animal Studies

The evidence for the carcinogenic potential of MC is primarily based upon chronic studies in rodent species. Table 4 contains a summary of the major bioassays conducted thus far. These bioassays have been conducted in three rodent species (rat, mouse and hamster) using two routes of administration (oral and inhalation) and a wide range of doses (from 5 mg/kg/d, oral to 4000 ppm inhaled).

*a. Mouse studies.* Two chronic studies of the carcinogenicity of MC in the mouse have been completed. Investigators in the National Toxicology Program (NTP) study (Ex. 7-8) exposed male and female mice to inhalation concentrations of MC. The National Coffee Association (NCA) sponsored study (Ex. 7-179) looked at the response of mice which received MC by oral administration.

TABLE 4.—METHYLENE CHLORIDE LIFETIME BIOASSAYS

Reference	Species/Strain	Route & dosing schedule	Dosage (No. Animals)	Comments
NTP (1985)	B6C3F <sub>1</sub> mouse	Inhalation 6 hr/day, 5 days/week	0, 2000, 4000 ppm (50 mice/sex/dose).	Lung & liver tumors both sexes, both doses.
Serota (NCA) (1986)	B6C3F <sub>1</sub> mouse	Daily in water	0 (125M, 100F), 60 (200M, 100F), 125 (100M, 50F), 185 (100M, 50F), and 250 (125M, 50F) mg/kg.	No tumors.
NTP (1985)	Fischer 344 rat	Inhalation 6 hr/day, 5 days/week	0, 1000, 2000, and 4000 ppm (50 rats/sex/dose).	Mammary & integumentary fibromas and fibrosarcomas in both sexes.
Burek (DOW) (1980)	Sprague-Dawley rat	Inhalation 6 hr/day, 5 days/week	0, 500, 1500, and 3500 ppm (95 rats/sex/dose).	Malignant salivary gland tumors at 3500 ppm, dose-related increase in mammary tumors.
Nitschke (DOW) (1982)	Sprague-Dawley rat	Inhalation 6 hr/day, 5 days/week	0, 50, 200, and 500 ppm (70 rats/sex/dose).	No tumors.
Serota (NCA) (1986)	Fischer 344 rat	Daily in water	0, 5, 50, 125, and 250 mg/kg/d (135/sex at 0, 85/sex/dose).	No tumors.
Burek (DOW) (1980)	Syrian Golden hamster	Inhalation 6 hr/day, 5 days/week	0, 500, 1500, and 3500 ppm (90 hamsters/sex/dose).	No tumors.

F=Female.

M=Male.

NTP=National Toxicology Program.

NCA=National Coffee Association.

DOW=DOW Chemical Company.



i. *The NTP study.* In the NTP study (Ex. 7-8), groups of 50 male and 50 female B6C3F<sub>1</sub> mice were exposed to 0, 2000 or 4000 ppm MC, 6 hr/day, 5 days/week for 102 weeks. All animals were necropsied and examined histopathologically.

(A) *Lung tumors.* In treated male and female mice, the incidences of alveolar or bronchiolar adenomas were increased as compared with control. Both sexes of mice were also found to have a dose-related increased incidence of carcinomas of the alveolar/bronchiolar regions. In addition, there was an increased number of lung tumors per tumor-bearing animal (multiplicity of tumors) with increasing dose of MC.

(B) *Liver tumors.* In the liver, the toxic effects of MC were expressed as cytologic degeneration in male and female mice which was not present in the controls. An increased incidence of hepatocellular adenomas and carcinomas (combined) was observed in male mice. The incidence of hepatocellular carcinomas in male mice was statistically significantly increased at 4000 ppm. Female mice also experienced dose-related increases in the incidences of hepatocellular adenomas and carcinomas. As described in the lung tumor data, an increased multiplicity of liver tumors was found in both male and female mice.

The increases in tumor incidences presented here were observed when the treated groups were compared with concurrent and with historical control groups. The tumor rates for male mouse liver tumors and rat mammary tumors (especially in females) are normally high in control animals of these species. This sometimes makes it difficult to discern a

true dose response for a treatment group when concurrent control animals are used for comparison. When comparing tumors which have relatively high or variable background rates, the NTP has determined that it is appropriate to compare the tumor incidence of a treated group, not only to concurrent control animals, but also to historical controls. Historical control animals are defined as those animals of the same species and strain which have been used in previous chronic bioassays in the same laboratory. This practice provides a larger control group and increases the statistical stability of the tumor rates with variable background incidences. The increases in tumor rates observed in these studies were statistically significant when compared to historical or concurrent control animals.

The dose-related increase in the incidence of lung and liver tumors in mice, and the increased multiplicity of these tumors, present the strongest evidence for the carcinogenicity of MC. NTP concluded that based on the evidence from these lung and liver tumors, that there was clear evidence of the carcinogenicity of MC in both male and female mice.

ii. *The NCA study.* Serota et al. (Ex. 7-179) exposed male and female B6C3F<sub>1</sub> mice to target levels of 0, 60, 125, 185 or 250 mg MC/kg body weight/day in drinking water for 24 months. Females developed a statistically significantly increased trend toward survival in the treatment groups as compared to controls. No treatment related effects were noted on survival rates of the males in any exposure group. Both male and female mice were found to have an increased fatty liver at 250 mg/kg/day.

In the treated male mice, there was a marginally increased incidence of proliferative hepatocellular lesions. Incidences are presented in table 5. These lesions did not increase among treated females. The incidence of hepatocellular carcinoma in the high dose males was statistically significantly increased over the first control group, but when compared with all of the control animals (control groups 1 and 2), the difference disappeared. The authors also reported that the incidences of hepatocellular carcinomas and of adenomas or carcinomas (combined) were within the range of historical controls. This study did not demonstrate a clear relationship between MC exposure and carcinogenesis.

b. *Rat studies.*—i. *The NTP study.* NTP conducted a two-year bioassay examining the effects of inhalation of MC at 0, 1000, 2000 and 4000 ppm in F344 rats (Ex. 7-8). Body weights of all exposure groups were comparable. The highest dose female rats experienced reduced survival after 100 weeks of exposure.

(A) *Mammary tumors.* Incidence of mammary fibroadenomas alone and combined incidence of fibroadenomas and adenomas in male and female rats occurred with statistically significant positive trends (see table 6). The incidence in the high dose group in both sexes was statistically significantly higher than controls (concurrent and historical). When subcutaneous fibromas or sarcomas in the male rat, which were believed to have originated in the mammary chain, were included in comparisons, differences between control and exposed animals were even greater.

TABLE 5.—INCIDENCE OF TUMORS IN MICE INDUCED BY METHYLENE CHLORIDE

NTP mouse study			
Dose (ppm)	Alveolar/ Bronchiolar adenoma	Alveolar/ Bronchiolar carcinoma	Alveolar/ Bronchiolar adenoma or carcinoma
Male Mice:			
0	3/50	2/50	5/50
2000	*19/50	*10/50	*27/50
4000	*24/50	*28/50	*40/50
	Hepatocellular adenoma	Hepatocellular carcinoma	Hepatocellular adenoma or carcinoma
Male Mice:			
0	10/50	13/50	22/50
2000	14/49	15/49	24/49
4000	14/49	*26/49	*33/49



Dose (ppm)	Alveolar/ Bronchiolar adenoma	Alveolar/ Bronchiolar carcinoma	Alveolar/ Bronchiolar adenoma or carcinoma
Female Mice:			
0	2/50	1/50	3/50
2000	*23/48	*13/48	*30/48
4000	*28/48	*29/48	*41/48
	Hepatocellular adenoma	Hepatocellular carcinoma	Hepatocellular adenoma or carcinoma
Female Mice:			
0	2/50	1/50	3/50
2000	6/48	*11/50	*16/48
4000	*22/48	*32/48	*40/48
Dose (ppm)	Alveolar/Bronchiolar or hepatocellular adenoma or carcinoma		
	Male	Female	
Combined Tumors:			
0	27/50	5/50	
2000	34/49	*36/48	
4000	*45/49	*45/47	
Dose (mg/kg)	Serota mouse study—NCA		
	Hepatocellular adenoma	Hepatocellular carcinoma	Hepatocellular adenoma or carcinoma
Male Mice:			
0	10/125	14/125	24/125
60	20/200	33/200	51/200
125	14/100	18/100	30/100
185	14/99	17/99	31/99
250	15/125	23/125	35/125

1. For inhalation studies, adjusted dose was calculated as  $d(\text{mg/kg/day}) = d(\text{ppm}) \times (1.2 \times \text{mol. wt. of air}) \times \text{breathing rate} \times \text{hrs. of exposure} / 24 \times \text{days of exposure} / 7 \div \text{body wt.}$

2. Incidence expressed as number of animals with response per number of animals examined for the response.

\* Statistically significant, using Fischer's Exact Test and a Bonferroni correction, at the .05/r level, where r is the number of test doses. For data sets 22-26 a Chisquare approximation of the Fischer Exact Test is used due to large sample size.

TABLE 6.—INCIDENCE OF TUMORS IN RATS AND HAMSTERS INDUCED BY METHYLENE CHLORIDE

NTP rat study			
Dose (ppm)	Mammary adenoma or fibroadenoma	Mammary or subcutaneous adenoma, fibroadenoma or fibroma	
Male Rats:			
0	0/50	1/50	
1000	0/50	1/50	
2000	2/50	4/50	
4000	*5/50	*9/50	
Dose (ppm)	Mammary adenoma or fibroadenoma	Neoplastic nodules or hepatocellular carcinoma	
Female Rats:			
0	5/50	2/50	
1000	11/50	1/50	
2000	13/50	4/50	
4000	*23/50	5/50	
Burek rat study—DOW			
Dose (ppm)	Salivary gland sarcomas	Mammary tumors	Mammary tumors per tumor-bearing rat (multiplicity)
Male Rats:			
0	1/92	7/92	1.1
500	0/95	3/95	2.0
1500	5/95	7/95	1.6



## Burek rat study—DOW

Dose (ppm)	Salivary gland sarcomas	Mammary tumors	Mammary tumors per tumor-bearing rat (multiplicity)
3500	*11/97	14/97	1.2
Dose (ppm)	Mammary tumors	Mammary tumors per tumor-bearing rat (multiplicity)	
Female Rats:			
0	79/96	2.1	
500	81/95	2.7	
1500	80/96	3.1	
3500	83/97	3.5	

## Nitschke rat study—DOW

Dose (ppm)	Mammary adenoma, fibroadenoma or fibroma	Mammary tumors	Mammary tumors per tumor-bearing rat (multiplicity)
Female Rats:			
0	52/70	52/70	2.0
50	58/70	58/70	2.3
200	61/70	61/70	2.2
500	55/70	55/70	2.7

## Serota rat study—NCA

Dose (mg/kg)	Neoplastic nodules or hepatocellular carcinoma	Historical control incidence	
		Neoplastic nodules	Hepatocellular carcinomas
Female Rats:			
0	0/135	range=0-13% mean=6.3%	0-3% 1.7%
5	1/85		
50	4/83		
125	1/85		
250	*8/110		

## Burek hamster study—DOW

Dose (ppm)	Lymphosarcoma		
Female Hamsters			
0	1/91		
500	6/92		
1500	3/91		
3500	8/91		

1. For inhalation studies, adjusted dose was calculated as  $d(\text{mg/kg/day}) = d(\text{ppm}) \times (1.2 \times \text{mol. wt. of air}) \times \text{breathing rate} \times \text{hrs. of exposure} / 24 \times \text{days of exposure} / 7 \times \text{body wt.}$

2. Incidence expressed as number of animals with response per number of animals examined for the response.

\* Statistically significant, using Fischer's Exact Test and a Bonferroni correction, at the .05/r level, where r is the number of test doses. For data sets 22-26 a Chi-square approximation of the Fischer Exact Test is used due to large sample size.

(B) *Liver effects.* Liver toxicity was characterized by hemosiderosis, hepatocytomegaly, cytoplasmic vacuolization and necrosis in exposed male and female rats. Neoplastic nodules alone and combined incidence of neoplastic nodules and hepatocellular carcinomas in female rats occurred with significant positive trends by the life table test (see table 6). Pair-wise comparisons did not indicate any statistically significant effects at any one dose. Although this is suggestive of a carcinogenic response in the female rat liver, NTP did not use this response in their determination of the carcinogenicity of MC.

NTP based its determination of the carcinogenicity of MC in the rat on the mammary tumor data described above. NTP has concluded that the increased incidences of mammary gland tumors in the female rats provided clear evidence of carcinogenicity and in the male rats, some evidence of carcinogenicity.

ii. *The high dose DOW study.* Burek et al. (Ex. 7-151) exposed male and female Sprague-Dawley rats to inhalation concentrations of 0, 500, 1500 and 3500 ppm MC, 6 hr/day, 5 days/week for 2 years. Female rats exposed to 3500 ppm had statistically significantly reduced survival during the final 6 months of exposure.

(A) *Mammary tumors.* The number of female rats with mammary tumors in this study did not increase with dose of MC. However, the number of tumors per tumor-bearing rat increased in a dose-related manner. Therefore, there was a statistically significant increase in total mammary tumors in the female rat due to MC administration (see table 6). This increase in total mammary tumors was also noted in the male rats exposed to MC, although the increases were not as pronounced as in the female rats.

(B) *Salivary gland tumors.* At 3500 ppm, male rats also exhibited a statistically significant increase in salivary gland sarcomas. The authors noted a high incidence of



sialodacryoadenitis (a viral infection of the salivary gland) in all exposure groups and both sexes during the first two months of the study. The authors believed that the salivary gland sarcomas were related to the presence of the virus, or perhaps a combination of the virus and MC exposure, since the incidence increased in a dose-related manner (see table 6). Female rats did not show an increase in salivary gland sarcomas even though they were also infected with the virus. Because of the confounding presence of the sialodacryoadenitis virus, and the apparent sensitivity of the males of the species, the biological significance of the salivary gland tumor is unclear. OSHA feels that because similar increases in these sarcomas were not observed in other rat bioassays (Exs. 7-8, 7-173, 7-180), in which the sialodacryoadenitis was not a factor, it is unclear whether the sarcoma incidence observed in the male rats should be used to quantify the carcinogenic response of the rats to MC.

*iii. The low dose DOW study.*

Nitschke et al. (Ex. 7-173) exposed male and female Sprague-Dawley rats to much lower concentrations of MC than used in the Burek study. In the Nitschke study, rats were exposed by inhalation to 0, 50, 200 or 500 ppm MC, 6 hr/day, 5 days/week for 2 years. The mortality experience for the exposed animals was equivalent to that of controls. A statistically significant increase in liver toxicity, characterized by cytoplasmic vacuolization and increases in the number of multinucleated hepatocytes, was observed in female rats at 500 ppm (see table 6). There was no increase in number of rats with tumors, but, consistent with the Burek study, the number of mammary gland tumors per tumor-bearing rat was increased in female rats exposed to 500 ppm MC. No statistically significant differences in tumor numbers or distribution were observed in male rats. Salivary gland sarcomas were noted in only two rats, one female at 50 ppm and one male at 500 ppm. These were not considered to be compound related.

*iv. The NCA study.* In a study sponsored by the National Coffee Association (Ex. 7-180), Serota et al. exposed male and female Fischer F344 rats to 0, 5, 50, 125 and 250 mg MC/kg body weight/day in drinking water for 2 years. Animals which received 125 and 250 mg/kg/day had lower body weights and a decreased food and water intake. Significant dose-related changes were observed in the livers of both sexes were observed at 50, 125 and 250 mg/kg/day. These changes were characterized by increased number of foci or areas of

cellular alteration and increased fatty liver. Increased incidences of neoplastic nodules and hepatocellular carcinoma were identified in females receiving 50 or 250 mg/kg/day (see table 6). However, the authors felt that these apparent increases were due to the unusually low incidences of neoplastic nodules and hepatocellular carcinoma in the concurrent control animals. When compared to historical controls, the differences between treated and control animals disappeared. The NTP has determined that it is appropriate to compare tumor incidence to the historical incidence in control animals in previous chronic bioassays in a particular laboratory. Even though there was a statistically significant dose-related trend observed when concurrent control animals were used, only one occurrence of neoplastic nodules was found at 125 mg/kg/day and the incidences in the 50 and 250 mg/kg/day groups were within the range of historical controls. OSHA believes that the data presented here are suggestive (but not conclusive) of a carcinogenic effect induced by MC.

*c. Hamster study.* In conjunction with the study on the chronic effects of MC in rats, Burek et al. (Ex. 7-151) examined the effects of MC inhalation in hamsters. Syrian golden hamsters received inhalation concentrations of 0, 50, 1500 or 3500 ppm MC 6 hr/day, 5 days/week for 2 years. The total number of benign tumors and the number of lymphosarcomas in the female group at 3500 ppm was increased when compared to control. This phenomenon is believed by the authors to be related to the significantly decreased mortality among the high dose female hamsters as compared with controls. Hamsters treated with MC experienced a dose-related decrease in the incidence and severity of amyloid deposits (thought to be a normal consequence of aging). The biological significance of this effect is unclear. No compound related toxicity or tumor was identified in this study.

*d. Summary of animal studies.* In summary, NTP found dose-related increases in lung and liver tumor incidences and multiplicity. These data were used to support the conclusion by NTP that the lung and liver tumor data in mice indicate clear evidence of carcinogenicity of MC. OSHA agrees with this conclusion. The mouse study of Serota et al. (Ex. 7-179) was conducted at exposure levels approximately an order of magnitude below those of NTP (Ex. 7-8). Because of the low doses employed, it is not surprising that Serota et al. could not detect a carcinogenic response in mice.

The rat studies described here (Exs. 7-8, 7-151, 7-173, 7-180) showed a clear pattern of liver toxicity and increased multiplicity of mammary tumors in female and male rats in both the Burek study (Ex. 7-151) and the NTP study (Ex. 7-8). The increased incidence of salivary gland sarcomas indicated in the Burek study were not repeated in other studies and are of questionable value in assessing carcinogenic response to MC because of the involvement of the sialodacryoadenitis virus. OSHA agrees with the determination of NTP that the rat data presented above indicate, in the female rats, clear evidence and, in the male rats, some evidence of carcinogenicity of MC.

In the Burek study (Ex. 7-151), hamsters showed no carcinogenic response due to MC exposure. The highest dose used in a chronic bioassay to determine carcinogenicity in a species should represent the maximum tolerated dose for that species. No evidence was presented to support the contention that 3500 ppm MC was the maximum tolerated dose for hamsters. In fact, the toxicity data seem to suggest that the hamsters (especially the females) do not suffer toxic effects 3500 ppm MC. The maximum tolerated dose generally produces signs of toxicity during a lifetime bioassay. In order to evaluate the carcinogenic potential of MC in the hamster during a lifetime bioassay, it is necessary to administer the compound at the maximum tolerated dose.

There has been some discussion of the appropriateness of using an increase in benign tumors (rat mammary tumors) as an indication of a carcinogenic response. OSHA agrees with NTP's contention that the increase in incidence or multiplicity of these benign tumors indicates clear evidence of carcinogenicity in the female rats. When the evidence for the carcinogenicity of MC derived from rat studies is combined with the data from the NTP mouse study, OSHA believes that the weight of evidence supports the conclusion that MC is an animal carcinogen and, therefore, a suspect human carcinogen.

## 2. Epidemiologic Studies

OSHA has reviewed epidemiologic studies of three industrial processes for which MC was the primary chemical exposure. Ott et al. (Ex. 7-76) and Lanes et al. (Ex. 7-260) examined the relationship between MC exposure and mortality among workers in a cellulose triacetate (CTA) fiber production plant. Friedlander et al. (Ex. 4-27) and Hearne et al. (Exs. 7-122, 7-163) investigated the mortality experience of a cohort of



workers exposed to MC during the production of photographic film. The National Paint and Coatings Association (NPCA) sponsored an epidemiologic study by SRI which looked at employees exposed to MC during paint and varnish manufacturing (Ex. 10-29b).

*a. Studies of fiber production workers.* Ott et al. (Ex. 7-76) studied the mortality of 1248 men and 971 women who worked for at least 3 months in the preparation and extrusion areas in one of two fiber production plants at any time between January 1, 1954 and January 1, 1977. The "exposed" cohort consisted of 1271 workers (551 men and 720 women) in a plant in Rock Hill, S.C. in which MC was the primary chemical exposure. Other exposures included methanol (at approximately 1/10 of the MC concentration), acetone (100 to 1000 ppm, lower concentrations in areas with higher MC exposures), and oil mists. MC TWAs for work stations in this plant ranged from 140 ppm MC to 475 ppm MC. These exposure concentrations were measured in 1977 and 1978 and assumed by the authors to be representative of ambient concentrations of MC throughout the history of the plant. Vital status for the exposed cohort could not be confirmed for 226 (18%) of these workers. There were 54 deaths recorded for the exposed cohort during the study period.

The reference plant, located in Narrows, VA, produced acetate fibers. No methylene chloride was used in this plant, and the primary chemical exposure was acetone. Of the 697 men and 251 women in this reference cohort, the vital status could be confirmed for all but 112 (12%) of the workers. Twenty-seven deaths were reported from this cohort.

Expected death rates for the two plants were calculated using U.S. general population statistics, and the mortality of the exposed cohort compared to the referent cohort. Among white males, statistically significant differences ( $p$  less than 0.05) in risk were observed for all causes of death (risk ratio (RR) = 2.2), for diseases of the circulatory system (RR = 2.2), and for all external causes of death (RR = 2.5). The risk ratio for malignant neoplasms in white males in exposed versus the referent group was not statistically significant (RR = 1.2). Females in the exposed group showed no statistically significant increases in mortality, but the RR for death by all causes was 1.3.

Although the purpose of choosing the two plants described above was to eliminate all differences in the populations except MC exposure, further examination of the data by the authors led them to conclude that the differences

in mortality experienced between the two plants were due primarily to geographical differences (48% rural population in the Rock Hill (exposed) plant, 85% rural in the Narrows (referent) plant). The authors believed these differences in geographical distribution of the populations of interest contributed to differences in death rates observed in this study and that these factors accounted for a greater proportion of the differences in death rates than MC exposure.

Although no increases in mortality from malignant neoplasms were observed in the MC exposed cohort, the authors noted that this study had little power to detect small to moderate increases in cancer rates. Also, the latency period for development of cancer in this study was relatively short, so that further follow-up studies would be necessary to examine any causal relationship between MC exposure and the development of cancer.

Lanes et al. (Ex. 7-260) extended the follow-up period for this cohort nine additional years, through September 1986. Therefore, this investigation increased the latency period during which cancer could develop and be detected. The statistical power to detect changes in chronic disease rates was also increased. To ensure comparability with the original study, Lanes et al. calculated the death rates for the exposed cohort through 1977. The close agreement of their results with those of Ott et al. (Ex. 7-76) verified that the methods of analysis of the two studies were similar. No attempt was made to extend the analysis of the referent group in the Narrows, VA plant. Death rate comparisons were based on U.S. general population statistics and death rates for York County, S.C. (in which 95% of the MC exposed cohort resided). Cohort members made up less than 4% of the total York County population.

When comparing disease occurrence between workers and the general population, the "healthy worker effect" must be considered; that is, workers, especially those in demanding or strenuous jobs, must have and maintain a degree of good health in order to perform and keep their jobs. Considering that the overall health of these workers is generally better than the overall health of the general population, a significantly elevated SMR for a worker population, when compared to the general population, is that much more compelling. Therefore, OSHA looks with particular interest at SMR data which show a significant excess of deaths in worker populations when compared to general population rates.

The total number of deaths increased from 54 in 1977 to 123 in 1986. Expected mortality was 121.4 (based on U.S. mortality rates, SMR=1.01) and 140.8 (based on mortality in York County, SMR=0.87). Total deaths from malignant neoplasms reached 28 (33 expected, U.S. and York County comparisons). Four deaths due to cancer of the liver and biliary passages were reported in the MC-exposed cohort. This was significantly different from the expected values of 0.53 deaths (based on U.S. statistics, SMR=2.40) and 0.66 deaths (based on York County data, SMR=2.32). The authors noted that all deaths occurred in workers who had been employed in the plant for more than 10 years and who died at least 20 years after they were hired. No deaths from these types of cancers were observed in the initial study. These results suggested that the latency period for these cancers may have been longer than the observation period in the initial study, and that cancers associated with MC exposure became observable during the follow-up study. This idea was further supported in that, in this relatively young population, only 9.68% of the cohort had died by the time of the analysis (4.25% in the original study), so that chronic effects, which are more likely to be observed in later life may not have had sufficient time to develop. Further follow-ups of the mortality experience of this cohort are necessary in order to confirm the increases in biliary/liver cancer described above and to identify any other chronic health effects due to MC exposure, especially neoplastic diseases.

The increase in liver and biliary cancer deaths is significant particularly in light of the fact that the liver was identified as a target site in the NTP rodent oncogenicity study. Also, three of these liver/biliary cancers were identified in individuals with apparently long durations of exposure and in all four of these employees, there was a long period between first hire and death from cancer. Although it must be taken into consideration that only a small number of cases of cancer have been identified in this study, that individual exposures to MC in this plant have not been well characterized, and that the effects of concurrent exposures to other chemicals (methanol, acetone, oil mists) have not been evaluated, OSHA believes that this study can be regarded as preliminary evidence of a positive human carcinogenic response to MC exposure.

OSHA is aware that additional epidemiological data are being collected from a MC-exposed cohort of cellulose



acetate fiber workers. The plant (closed since 1982) is located in Cumberland, MD, and was similar in operation and exposures to the Rock Hill, S.C. plant. It is the Agency's understanding that the same methodology will be used as employed in the previous study. OSHA will closely follow the progress of this study and evaluate any results which may become available during the rulemaking process.

*b. Studies of film production workers.* Friedlander et al. (Ex. 4-27) and Hearne et al. (Exs. 7-122, 7-163) have studied the mortality experience in the film coatings operations of a Kodak film production plant in Rochester, NY. The cohort studied consisted of 1013 men employed for at least one year in the roll coating division at any time between January 1964 and December 1970. Cohort members were followed through 1988.

The comparison groups consisted of the male population of New York state outside of New York City, and an industrial control group of 40,000 men employed at Kodak Park in Rochester, but not working in the roll coating division. This industrial control group was useful in correcting for the healthy worker effect discussed previously. This effect can mask small increases in mortality due to occupational factors when comparisons are made to general population mortality.

Exposure characterizations for each job site were made through extensive personal and ambient air sampling. The mean TWA for the cohort described was 26 ppm. The mean tenure in the roll coating division was 23.1 years. Employment history and exposure profile was constructed for each employee. The latest follow-up study (Ex. 7-163) accumulated 22,006 person-years of follow-up. The total number of deaths was 238 (23.5% of the cohort) and determination of vital status was greater than 99%.

In the latest update (Ex. 7-163), no statistically significant increases in cause-specific or total mortality was associated with MC exposure. The cohort was analyzed by lifetime MC exposure (dose) and latency (time from first exposure). No dose-related or latency-related trends were identified for cause-specific death rates. In earlier updates of the original study (Ex. 7-122), an elevated number of pancreatic cancers were reported in the MC exposed cohort. The excess pancreatic cancers did not meet the statistical criteria for significance set by the authors for non-hypothesized causes of death. Hypothesized causes of death were based on the metabolism of MC to CO and subsequent cardiac stress (ischemic heart disease) and cancer

target sites identified in the NTP rodent bioassay (liver, lung and breast). Death rates from hypothesized causes were required to meet a one-tailed  $p$  less than 0.05 to be statistically significant, while non-hypothesized causes of death were required to meet a two-tailed  $p$  less than 0.01 to be significant. The purpose of this increased stringency for non-hypothesized causes of death was to reduce the probability that a difference in death rates would be determined to be significant when it was a chance occurrence. As the number of outcomes examined (cause-specific deaths) is increased, the probability that a death rate will be elevated or depressed by chance alone, increases. The suggestive increases in the rates of pancreatic cancers observed in the earlier studies has become less statistically significant with time. In the latest update the SMR for pancreatic cancer was 1.9 (8 cancers observed versus 4.2 expected (NYS and Kodak Park comparators),  $p=0.13$ ). No additional pancreatic cancers have been observed since the previous update in 1984 (3 expected). This lends further credence to the contention that the suggestive elevation in pancreatic cancers was not due to MC exposure.

The overall mortality of this cohort was statistically significantly less than both comparison groups (SMR=0.72 based on NYS statistics and SMR=0.80 based on Kodak Park data). The explanation for this deficit in mortality among MC exposed workers has not been explained.

*c. Study of workers in paint and varnish manufacturing.* The NPCA submitted an epidemiological study by SRI (Ex. 10-29b) that examined 16,243 employees who worked for at least one year in the manufacture of paint or varnish. MC exposure was not measured for the cohort studies, however, the authors stated that typical exposure to MC was below 100 ppm. The overall mortality for this cohort compared favorably with U.S. general population death rates. This "healthy worker effect" is described above in the discussion of the cellulose acetate fiber workers. No statistically significant excess cancers were identified in the exposed cohort; however, marginally elevated SMRs were identified for cancer of the skin, lung, colon/rectum and liver. The authors felt that these were sufficiently elevated to warrant further study. Because of the multiple exposures in these workers, lack of individual exposure data and lack of statistically significant excesses of specific cancers, there is no evidence of an association between MC exposure and cancer in this cohort.

OSHA believes that while all workers in the study were potentially exposed to MC, the subcohort of workers who cleaned tubs and tanks had the greatest exposure. This subcohort numbered only 238 of the 16,243 total workers. Although there are limited data available for this subcohort and none of the SMRs achieve statistical significance, the Agency notes that there were 4 malignant neoplasms of the pancreas (1.93 expected) and 15 malignant neoplasms of digestive organs and peritoneum (10.66 expected).

In summary, there is no evidence of statistically significant excess of cancers in the study of workers in paint and varnish manufacture and no evidence for an association of MC exposure and cancer for this industry. This study does point out, however, the need for follow-up investigations of this cohort, including documentation of exposures (to all chemical agents) and identification of confounding factors.

*d. Summary of epidemiological studies.* OSHA preliminarily believes that the Kodak and NPCA studies indicate no increase in mortality associated with MC exposure. This result is not inconsistent with the findings of Cohen (Ex. 7-75) because of the much greater MC exposures likely to have been experienced in the fiber production workers than described for the film production workers or workers in paint and varnish manufacture. The low average exposure levels in the Friedlander and Hearne and NPCA studies and relatively small population with higher exposures to MC limit the power of these studies to detect small to moderate increases in cancer rates.

In summary, an epidemiological study of fiber production workers has shown an increased incidence of liver/biliary cancer subsequent to relatively high MC exposures (140-475 ppm TWA). A second epidemiologic study of workers in a film production plant showed no increase in any cause specific death rates. These workers were exposed to much lower MC concentrations (26 ppm TWA). A third study of workers in paint and varnish manufacture also showed no increase in any cause specific death rates associated with MC exposure. OSHA notes that individual MC exposures were not documented and that workers in this study were likely exposed to other chemical agents. OSHA preliminarily concludes that based on the increased incidence of liver/biliary cancers in the fiber production workers, there may be an increased risk of cancer in these worker populations causally related to MC exposure.



### 3. Mutagenicity Studies

Mutagenicity and genotoxicity studies are useful in describing the possible carcinogenic mechanism of action of MC. Evidence for the interaction of MC or MC metabolites with DNA (producing mutations or toxicity) supports a genotoxic mechanism for the carcinogenic action of MC, rather than a non-genotoxic action (i.e., by acting as a promoter, increasing cell turnover). EPA has reviewed the literature concerning the mutagenic potential of MC in their Health Assessment Document for Dichloromethane (Methylene Chloride) (HAD) (Ex. 4-5) and the studies conducted by ECETOC in the Technical Analysis of New Methods and Data Regarding Dichloromethane Hazard Assessments (Ex. 7-129). OSHA agrees with EPA's assessment of the various studies, the results of which are summarized below.

*a. Bacterial studies.* Investigations of the induction of mutagenicity by MC were performed using the *Salmonella typhimurium* histidine reversion assay. MC tested positive for mutagenesis in all of the studies using *Salmonella* TA100, TA1535 or TA98 with and without mammalian metabolic activation of MC, when assays were performed in sealed, gas tight exposure chambers (Ex. 4-5). In studies which presented sufficient data for analysis, clear dose responses were apparent. A 10-fold or greater increase in revertants was observed at the highest doses compared to negative controls. Barber et al. (Ex. 7-190) conducted their tests in a chemically inert, closed incubation system and analyzed concentrations of MC in the vapor phase and the aqueous phase of a test plate. Based on this quantitative determination of the MC dose (115  $\mu\text{mol}/\text{plate}$ ), MC was considered to be a weak mutagen for *Salmonella* under the conditions of the test.

The relevance of the mutagenicity data derived from *Salmonella* has been questioned. However, bacterial metabolism of MC is very similar to that of mammalian systems (*Salmonella* metabolizes MC to  $\text{CO}_2$  and CO, apparently by pathways similar to those in mammals). Because of the reactivity of the metabolic intermediates of these pathways (formaldehyde, formyl chloride and S-chloromethylglutathione), and the proximity of the bacterial DNA to the cytoplasmic enzymes, it has been suggested (Ex. 10-18) that bacteria may be more susceptible to mutagenicity than more complex organisms, which would be protected by sequestration of the DNA in the nucleus of the cells. The highly reactive metabolites would then

be more likely to react with other cellular constituents before they could cross the nuclear membrane to interact with DNA.

*b. Yeast and Drosophila studies.* In yeast, two studies were conducted, one by Simmon (Ex. 7-241) on the mitotic recombination potential of yeast after exposure to MC and one by Jongen (Ex. 7-191) on the potential for gene conversion, reverse mutations and mitotic recombination in yeast. The former study was judged by the authors to show no mutagenic potential of MC in yeast. The latter study produced positive evidence of the mutagenicity of MC. The EPA felt that differences in the results of these two studies were most likely due to different yeast strains used, differences in exposure times and differences in incubation temperature. It is interesting to note that the mutagenic potential of MC correlated with the cytochrome P450 metabolic ability of each yeast strain (Ex. 4-5).

In 1981, Gocke et al. (Ex. 7-193) tested the mutagenicity of MC by examining induction of sex-linked recessive lethal mutations in *Drosophila*. MC was administered in solutions of 2% DMSO and 5% saccharose. The highest dose was thought to be close to the  $\text{LD}_{50}$ . A dose-related incidence of lethal mutations was reported. This study demonstrated that MC was mutagenic to sperm in *Drosophila*.

*c. Studies in mammalian cells.* MC has been tested for mutagenicity in several mammalian cell culture test systems. In 1980, Jongen et al. (Ex. 7-49) incubated CHO and V79 cells with concentrations of MC up to 5%. After exposure to MC, cells were selected for expression of the HGPRT gene locus (a forward mutation). MC did not increase the mutation frequency of either cell line. EPA suggested that, in order to evaluate the mutagenic potential of MC in this system, the test dose should be higher than that used in the study, because minimal cytotoxicity was observed in the cells at all of the doses given. Cell survival was decreased only 20% by the highest dose of MC.

Several investigators have studied the potential for MC to induce chromosomal aberrations. In an experiment conducted by Thilagar and Kumaroo (Ex. 7-192), MC induced a dose-related increase in chromosome aberrations in CHO cells. This response was not altered by the presence of an exogenous metabolic activation system (S-9 mix from Aroclor-induced rat livers).

Burek et al. (Ex. 7-151) examined the bone marrow of rats exposed to concentrations of 0, 500, 1500 or 3500 ppm MC 6 hr/day 5 days/week for 6

months. No increases in the frequency of abnormal cells or in the frequency of any specific aberration were reported in treated animals compared to the controls. However, in this experimental protocol it is necessary for the active metabolite of MC to reach bone marrow and interact with the DNA. There is no evidence that bone marrow is a target for MC, that MC is metabolized in bone marrow, or that metabolites produced in distant sites are stable enough to be transported to the bone marrow to exert a toxic effect. Therefore, it is predictable that MC would not exhibit a genotoxic effect in this assay.

Two studies of the ability of MC to cause micronuclei in polychromatic erythrocytes (PCE) (a measure of the genotoxicity of a compound) were evaluated. Gocke et al. (Ex. 7-193) examined the effects of three dose levels of MC (850, 1700, and 3400 mg/kg in 2 i.p. injections 24 hours apart). An increase in PCEs with micronuclei was observed at the two highest doses, but a dose-response relationship was not demonstrated. Also, the highest response observed was not greater than two times the control values. EPA considered these results inconclusive, but suggestive of a positive response. In 1986, Sheldon et al. (Ex. 8-30) also evaluated the potential for MC to induce micronuclei in PCEs. This study was determined to be negative for MC. These studies required MC-induced toxicity in the bone marrow (the site of erythrocyte formation), which has not been identified as a target tissue for MC toxicity. The mouse micronucleus assay may not be a sensitive indicator of the genotoxic potential of MC because, as indicated above, there is no evidence that bone marrow is a target for MC toxicity and the concentration of MC metabolites formed in other organs such as lung and liver which do reach the bone marrow, may not be in sufficient quantities to elicit a positive response in this assay.

Three studies have examined the effects of MC on the induction of sister chromatid exchanges in the DNA of mammalian cells in culture. MC was shown to induce SCEs in V79 cells by Jongen et al. (Ex. 7-49). This induction was dose-related and statistically significant at  $p$  less than 0.001. In a similar study, Thilagar and Kumaroo (Ex. 7-192) judged their study of MC induction of SCEs in CHO cells to be negative. However, slight dose-related increases in SCEs were reported. These increases did not achieve statistical significance, but were suggestive of a positive response. The doses used in this study were lower than in the study by



Jongen et al. In a study by McCarroll et al. (Ex. 7-237), dose-related increases in the SCEs in CHO cells were reported at higher doses (up to 7% atmosphere) than used in the Thilagar and Kumaroo experiments (Ex. 7-192). Based on the evidence from these three studies, MC has been determined to cause DNA damage resulting in SCEs in cultured mammalian cells.

Several studies were conducted to determine the potential for MC to induce DNA repair, expressed as unscheduled DNA synthesis (UDS). Jongen et al. (Ex. 7-49) measured UDS and inhibition of DNA synthesis in V79 cells and primary human fibroblasts *in vitro*. MC had no detectable effect on UDS in either cell line. Inhibition of DNA synthesis was detected, but this effect was demonstrated to be a toxic effect of MC on the metabolism of MC and not a direct action of MC on DNA synthesis. In 1981, Perocco and Prodi (Ex. 7-189) also found no differences in *in vitro* DNA repair rates between MC-treated and control human lymphocytes.

Trueman et al. (Ex. 8-16) examined the effects of MC on UDS *in vitro* and *in vivo*. In the *in vitro* study, rat and mouse primary hepatocytes were exposed to 500, 1000, 2000 or 4000 ppm MC for 2 or 6 hours, and evaluated for UDS. The authors judged this study to be negative because, although the data is suggestive of a dose response, the results did not achieve statistical significance. The results may have had greater statistical power if higher doses were used. The study can be criticized on the grounds of dose selection because appropriate doses in *in vitro* UDS experiments are generally chosen as fractions of a dose which produces profound cytotoxic effects. The very limited cytotoxicity described in this study indicates that the doses used should most likely have been much higher. This study had little power to predict MC effects on UDS. In the *in vivo* UDS experiments, rats and mice were exposed for 2 or 6 hours to 2000 or 4000 ppm MC. Hepatocytes were isolated from these animals and the DNA repair rates evaluated by measuring UDS. The results of this study show no effect of MC on DNA repair rates. However, the appropriateness of this protocol in the assessment of MC genotoxicity has been called into question by the EPA (Ex. 7-128). EPA states that the study of UDS *in vivo* is only justified when metabolism of a toxic agent is thought to occur outside the liver and the resulting metabolites are stable enough to be transported to the liver where they can interact with the DNA and cause genotoxic damage. The evidence accumulated concerning

the metabolism of MC, on the other hand, suggests that MC is metabolized in the liver and lung, and that the toxic metabolites are very short-lived (too short-lived to be transported outside the metabolizing organ). In addition, the doses used in this study, as in the *in vitro* work, were too low. The basis for choosing these doses was the NTP chronic bioassay. Doses in the NTP study were designed to be administered to animals 6 hr/day for two years. Doses appropriate in a chronic study are generally too low to elicit detectable genetic changes in a short-term genotoxicity assay.

Lefevre and Ashby (Ex. 8-31) examined the effects of MC on the induction of cell replication by measuring the induction of S-phase hepatocytes by exposure to MC *in vivo*. Mice were exposed to 4000 ppm MC for 2 hours. This exposure was followed by *in vivo* radiolabelling of DNA and autoradiography of isolated hepatocytes. In two of three experimental protocols small, but statistically significant, increases in replicating hepatocytes were observed. The authors alluded to the possibility that the carcinogenic action of MC is the result of a non-genotoxic event which increases cell turnover, and therefore, tumorigenicity. However, the low dose used (4000 ppm is appropriate for a chronic bioassay, but not in short term studies) and the small effect observed gave this study little power to discriminate between weakly genotoxic and non-genotoxic activity.

The ability of a compound to bind covalently with DNA is one measure of its potential for genotoxicity. Although it is not necessary for a compound to bind to DNA to cause mutation, there are many examples of compounds which act in this manner. Green et al. (Ex. 8-16d) described experiments which test the ability of MC to bind covalently with DNA *in vivo*. Mice were exposed to 4000 ppm <sup>14</sup>C-labelled MC and the liver DNA was examined for alkylated bases. A confounding factor in this protocol was that MC is metabolized to one-carbon compounds which may then enter the normal metabolic pathways for DNA. This results in radioactivity from labelled MC associated with all of the normal DNA bases as well as with any alkylation products. This problem was assessed by a second protocol in which DNA was labelled with <sup>14</sup>C-formate (which labels all normal DNA bases except cytosine) and then the animals were exposed to 4000 ppm unlabelled MC. No alkylated bases resulting from MC exposure were detected in this study.

The sensitivity of these experiments was questioned because of the low dose of MC used (one dose of 4000 ppm), but also because of the apparent insensitivity of the analytical methods. In these experiments, no 5-methylcytosine was detected. This normally-occurring base is labeled at the 5-methyl position by <sup>14</sup>C-formate and comprises approximately 3% of the normal DNA cytosines. Using the exposure protocol outlined by the authors, alkylated bases would be expected to occur at much lower frequencies than 5-methylcytosine in the DNA, especially if MC is believed to be a weak alkylating agent. If a normal minor base such as 5-methylcytosine cannot be detected by the methods used, the presence of any alkylated bases, especially from a weakly genotoxic agent, could not possibly be detected. OSHA disagrees with the authors findings that this study presents evidence of the lack of covalent binding of MC to DNA.

d. *Summary of mutagenicity studies.* In summary, OSHA believes that the evidence reported above indicates that MC is mutagenic in bacterial and lower eukaryotic systems, and has been shown to be weakly genotoxic in some mammalian systems. OSHA disagrees with the conclusion of Broome et al. (Ex. 4-65) that "the genetic rationale for a carcinogen risk assessment for DCM (MC) is inappropriate." Negative findings in several of the studies described here have been explained by inappropriate dosing or inappropriate protocol. The documentation of positive responses in the production of mutations in bacteria, yeast and *Drosophila*, chromosomal aberrations in CHO cells and SCEs in CHO and V79 cells and equivocal responses in other systems, indicate the potential genotoxicity of MC. These results support the rationale for development of a cancer risk assessment based on the genotoxic mechanism of action of MC.

#### D. Other Toxic Responses

##### 1. CNS Toxicity

a. *Animal studies.* There is little data available describing behavioral or neurological effects of MC in animals other than the induction of anesthesia at high doses (greater than 1000 ppm). The data base describing the behavioral and neurological effects in humans from experimental and occupational exposures to MC is fairly large. Therefore, the value of additional behavioral data for rodents (measured as increased sleeping time or decreased running time) in assessing human risk from exposure to MC is questionable.



Studies of biochemical changes in the brains of rodents exposed to MC, on the other hand, could be very important in determining the mechanism of action of MC neurotoxicity and the reversibility of chronic effects of MC exposure.

In a study by Savolainen et al. (Ex. 7-178), increased levels of acid proteinase in rat brains, but no change in brain RNA levels, were reported at 3 and 4 hours on the fifth day of exposure to 500 ppm MC, 6 hours/day. The authors suggest that the increase in acid proteinase may be due to increased levels of CO from metabolism of MC. The induction of a measurable change in the biochemistry of the brain after a relatively low concentration of MC (the current PEL) and the short duration of exposure suggests that human exposures to these levels may similarly induce biochemical CNS changes. More research in these areas is necessary to assess the biological significance of these findings.

In a study of long term exposure to MC, Rosengren et al. (Ex. 7-56) looked at the effects of MC on glial cell marker proteins and DNA concentrations in gerbil brains. Animals were exposed continuously to 210, 350 or 700 ppm MC. Because of high mortality in the 2 higher doses, no data was collected at 700 ppm and exposure was terminated after 10 weeks at 350 ppm. Exposure to 210 ppm was continued for three months. Exposure to MC was followed by four months of no exposure before animals were examined for irreversible CNS effects. The authors found increased levels of glial cell marker proteins in the frontal cerebral cortex and sensory motor cortex after exposure to 350 ppm MC. These findings are consistent with glial cell hypertrophy or glial cell proliferation. Levels of DNA were decreased in the hippocampus of gerbils exposed to both 210 and 350 ppm and in the cerebellar hemispheres after 350 ppm MC. Decreased DNA concentrations indicate decreased cell density resulting from cell death or inhibition of DNA synthesis.

The neurotoxic mechanism of action of MC in gerbil brains is not understood. However, since the metabolism of MC to CO was determined to be saturated at both 210 and 350 ppm (COHb levels were equivalent at both exposure concentrations), the toxic effect of MC was attributed to either the parent compound or metabolism by a second pathway (e.g. the GST pathway). It would be interesting to examine the effects of MC on these parameters using a daily exposure protocol instead of continuous exposure to determine if the irreversible effects observed would be

diminished. It is not known at the present time whether a daily "recovery period" would increase the reversibility of these effects or not. Also, replication of these effects in other species is important, in order to establish that this effect is not specific to the gerbil (in which no other MC toxicity studies have been conducted).

In summary, OSHA believes that this evidence is highly suggestive of the susceptibility of the CNS to reversible and irreversible effects due to MC exposure. Biochemical studies of this nature are critical in elucidating the mechanism of action of MC on a biochemical level, and extrapolation of these effects to human exposures.

*b. Human studies.* The CNS depressant effects of MC have been well described in the literature (Exs. 7-4, 7-153, 7-154, 7-160, 7-175, 7-182, 7-183, 7-184). In the early part of this century, MC was used as an inhalation anesthetic, but abandoned because of the excitatory responses at doses required for anesthesia and the narrow margin between induction of anesthesia and death.

Accidental human overexposures to MC (Exs. 7-18, 7-19) have indicated that acute, high exposures (greater than 10,000 ppm) can result in narcosis and death. Inhalation of much lower concentrations of MC are associated with less severe CNS effects. In humans, CNS effects have been noted after experimental exposures to as low as 200 ppm (Ex. 7-175) and occupational exposures to as low as 175 ppm (Ex. 7-153).

*i. Experimental studies.* Putz (Ex. 7-175) described CNS deactivation, decreased eye/hand coordination and decreased vigilance, speed and precision during exposure to 200 ppm MC for 4 hours. Deficits in eye/hand coordination and dual task performance were larger than those produced by exposure to 70 ppm CO alone. The COHb resulting from these two exposures was approximately equal, leading to the conclusion that the CNS effects produced by MC were the result of the direct toxicity of MC in addition to the toxicity due to COHb.

Stewart (Ex. 7-4) found increased lightheadedness and changes in visual evoked response (a measure of CNS activation) after the first hour of a two hour exposure to 986 ppm and the same types of changes after 1 hour exposure to 514 ppm followed by approximately 15 minutes of a second 1 hour exposure to 868 ppm. In 1973, after exposure to a complex schedule of doses from 1 hour per day at 50 ppm to 7.5 hours per day at 500 ppm, Stewart (Ex. 7-5-R0327)

demonstrated changes in the visual evoked response that were dose-related, but no effects on reaction times or performance of various tasks.

Gamberale et al. (Ex. 7-160) exposed 14 subjects to four 30 minute intervals, of increasing MC concentration increments from 250 to 1000 ppm (total exposure duration of 2 hours). The authors found a favorable change in mood, decreased heart rate and an increased variability in reaction time only at 1000 ppm. They found no statistically significant dose-response trend. However, since each dose was only experienced for one 30 minute interval, the power of this study to detect dose-related changes was low.

In contrast to the reported negative findings of Gamberale et al., Winneke (Ex. 7-184) performed a series of experiments on male and female volunteers which demonstrated a CNS depression after exposure to 300 and 800 ppm. This depression was manifested as decreased vigilance and decreased critical flicker fusion at both doses, after approximately 1.5 hours of a 3 hour exposure to 300 ppm MC. Decreased vigilance, psychomotor speed and reaction times were also measured during a 4 hour exposure to 800 ppm. A second study by Winneke (Ex. 7-182) compared the effects of MC at 300, 500 and 800 ppm to those effects produced by 50 and 100 ppm CO. These doses of CO produced a COHb level in the range of that produced by the MC doses. COHb was not measured in these experiments, but estimated to be equivalent whether exposure was to CO or MC. Winneke described increased deficits during MC exposure as compared with CO exposure. The authors concluded that MC produced greater toxicity than could be explained by metabolism to CO alone. Although this conclusion is the same as that forwarded by Putz (Ex. 7-175), the study is weakened by the fact that actual COHb levels were not measured.

These experimental studies show that there are definite signs of CNS depression as low as 200 ppm for 4 hours and 300 ppm at 1.5 hours of exposure. In the experiments which were sensitive enough to detect subtle CNS effects, a no observed effect level was not determined, because the lowest experimental concentration used (200 ppm) elicited CNS changes. It is reasonable to suggest that MC may cause CNS effects similar to those observed at 200 ppm, at lower exposures or after exposure for shorter durations, but OSHA is not aware of any experimental study of this type which



has investigated the CNS effects of MC at these levels.

#### ii. Occupational exposure studies.

Kuzelova et al. (Ex. 7-26) examined workers in a film production plant who were exposed to MC at concentrations from 29 to 4899 ppm. There were cases of frank intoxication and large numbers of workers with neurological symptoms of MC toxicity. The mechanism for controlling exposure to these high industrial levels was removal of the affected employee to fresh air until he or she had recovered sufficiently to resume working. The effects described in this study were thought to be completely reversible, even after intoxication. No other toxicity associated with MC exposure was observed.

Cherry et al. (Ex. 7-154) studied the effects of occupational exposure to much lower concentrations of MC in two populations exposed to MC. In the 1981 study, the authors found a marginal increase in self-reported neurological symptoms among exposed workers. This increase disappeared when an appropriate reference group was used for comparison. However, in a similar study in 1983, Cherry (Ex. 7-153) showed statistically significant increases in tiredness and deficits in reaction time and digit symbol substitution which correlated to MC in blood. Exposures for this population ranged from 28 to 175 ppm for the full shift. This study demonstrated CNS effects due to occupational MC exposures below 200 ppm (the lowest dose which was administered in the experimental studies).

All of the CNS effects described above are currently thought to be completely reversible; however, there are some reports of a neuropathy associated with chronic occupational exposure to various solvents. Hanke (Ex. 7-195) and Weiss (Ex. 7-196) have described a diffuse toxic brain damage which is associated with chronic exposure to MC. Weiss (Ex. 7-196) described the case of a 39 year old chemist who worked for 5 years with airborne concentrations of MC as high as 660 ppm to 3600 ppm in a room with poor ventilation. After 3 years of exposure, the worker developed neurological symptoms, characterized by restlessness, palpitations, forgetfulness, poor concentration, sleep disorders, and finally, acoustical delusions and optical hallucinations. No hepatic damage or cardiac toxicity was found. At the first appearance of symptoms, cessation of exposure produced an immediate cessation of symptoms. Later, longer and longer periods were required after termination

of exposure in order to alleviate the symptoms. The increasing persistence of symptoms is consistent with a diagnosis of toxic encephalosis.

Hanke et al. (Ex. 7-195) examined 32 floor tile setters who were exposed primarily to MC at concentrations from 400 to 5300 ppm for an average tenure of 7.7 years. Clinical examination of 14 of the workers who had neurological symptoms (headache, vertigo, sleep disturbance, digestive complaints and lapses in concentration and memory) revealed changes in the EEG patterns of the exposed workers which persisted over a weekend pause in exposure. These EEG changes were characteristic of a toxic encephalosis produced by chronic intoxication with a halogenated solvent (MC). The persistence of the EEG changes over the weekend break excluded an acute effect of MC exposure on EEG patterns. (Additional changes in the EEG found during exposure could be attributed to an acute effect of MC). Although these studies represent a small number of cases with very high chronic exposures, the evidence is suggestive of a relationship between chronic MC exposure and toxic encephalosis.

In a case study report, Barrowcliff et al. (Ex. 7-123) attributed cerebral damage in a case study to CO poisoning caused by exposure to MC. Axelson (Ex. 7-150) has described an increased number of neuropsychiatric disorders among occupations with high solvent exposures. These studies, coupled with the limited animal data on the irreversible effects of MC, provide suggestive evidence of a permanent toxicity which may be the result of chronic exposure to MC.

#### c. Summary of CNS toxicity studies.

The primary concern surrounding the CNS toxicity of MC is the CNS deactivation that has been described in humans as low as 175 ppm (8 hour TWA). This depression in CNS activity can be expressed as increased tiredness, decreased alertness and decreased vigilance. These effects could compromise worker safety by leading to an increased likelihood of accidents during MC exposure. A second concern is the potential for development of irreversible brain damage as described by Hanke and Weiss (Ex. 7-195, 7-196). In these studies, the case numbers are small, the exposures to MC very high and more work is necessary to adequately describe the mechanistic relationship of the toxic encephalosis to MC exposure. However, the evidence that solvent-associated neuropathy exists justifies OSHA's action for

reevaluating the adverse health effects of MC.

#### 2. Cardiac Toxicity

Since MC is metabolized *in vivo* (in animals and humans) to CO and CO<sub>2</sub>, it is reasonable to suspect that cardiovascular stress known to occur from CO exposure may occur with exposure to MC as well (Ex. 7-73, 4-33). Carbon monoxide successfully competes with oxygen and blocks the oxygen binding site on hemoglobin, effectively reducing the delivery of oxygen to the tissues. Hemoglobin has an affinity for CO that is 240 times its affinity for oxygen. This means that even at low ambient CO concentrations, CO can outcompete oxygen for the hemoglobin binding sites. The most severe result of this binding is the reduction of oxygen supply to the heart itself, which can result in myocardial infarction (heart attack) (Ex. 4-033).

a. *Animal studies.* In the acute and chronic animal studies conducted to date, there is no evidence of a direct effect of MC on the heart. In lethal doses of MC, death is primarily the result of CNS and respiratory depression (Exs. 7-27, 7-28). Chronic studies (in which COHb levels have been maintained at 10% and higher) (Exs. 7-3, 7-8, 7-14, 7-130, 7-151) have also shown no direct cardiotoxicity of MC.

Chlorinated solvents have been shown to sensitize the cardiac tissue to epinephrine-induced fatal cardiac arrhythmias (Ex. 7-226). However, the evidence concerning MC is limited because the animals were susceptible to the narcotic effects of MC at a dose below which cardiac sensitivity was initiated. This suggests that this finding is of limited usefulness in occupational settings, because MC concentrations high enough to produce narcosis would be intolerable in a work environment.

b. *Human studies.* Because of the large numbers of American workers with silent or symptomatic heart disease, human populations may be more susceptible to the cardiac toxicity of MC than laboratory animals. Elevated COHb has been measured in humans experimentally and occupationally exposed to MC (Exs. 7-4, 7-5-R0327, 7-102, 7-115, 7-157, 7-159, 7-169, 7-174, 7-176). The effect of elevated CO exposure on the heart has been well established. Atkins and Baker (Ex. 7-198) described two cases of myocardial infarction in workers subsequent to CO exposure. COHb was measured at 30% and 24% in these individuals. While lower levels of COHb (3-10%) (levels which may result from occupational exposure to CO or MC) have not been associated with



frank morbidity or mortality, COHb at these levels has been correlated with decreased exercise tolerance and increased anginal pain in individuals with coronary artery disease (Ex. 7-198).

Stewart et al. (Ex. 7-102) described a case of a 66 year old man who experienced three separate myocardial infarctions (the last one was fatal), each one after a 2 to 3 hour session of furniture stripping using a commercial paint remover formulation. Although the MC exposure and COHb levels were not measured, this case is highly suggestive of an association between MC exposure and cardiac stress. Welch (Ex. 7-73) described 144 case reports of clinical disease associated with MC exposure. Three of the cases were of cardiac symptoms which worsened upon exposure to MC; one was a myocardial infarction. MC exposure levels were not reliably measured in these cases, but these cases also suggest an association between MC exposure and cardiac stress.

DiVincenzo and Kaplan (Ex. 7-222) described the effects of smoking and exercise on the uptake, metabolism and excretion of MC. They found that exercise increases MC uptake and, subsequently, blood COHb levels through the metabolism of MC. The COHb levels due to smoking were found to be additive to the COHb produced by MC metabolism. This means that smokers or individuals engaged in physical exertion (as in a workplace), may be at increased risk from CO-induced toxicity from MC exposure. This is particularly true for individuals with silent or symptomatic cardiac disease who may be susceptible to the effects of CO at levels as low as 3%.

The two major epidemiological studies (in film coating and fiber production workers) (Exs. 7-75, 7-76, 7-122, 7-163) reported no increased cardiac mortality due to occupational exposure to MC. In the original study of the fiber production workers, Ott (Ex. 7-76) compared mortality from the MC exposed plant in South Carolina to a reference plant in Virginia. An increased risk ratio for ischemic heart disease was observed in the MC exposed workers compared to the reference population. The authors explained this disparity by examining geographical variability in the incidence of ischemic heart disease. The reference plant was found to have an unusually low (and unexplained) death rate due to ischemic heart disease. In an update of the study (Ex. 7-75), this contention was further supported when the exposed population was compared to the surrounding York County, S.C. population. No difference in ischemic

heart disease rates was detected between exposed workers and controls. The SMR was 0.94 (32 observed, 34.2 expected).

Further examination of the fiber production workers by Ott in 1977 (Ex. 4-33d) provided information on the cardiac response of 24 male workers during occupational exposures to MC. The workers were monitored using continuous ambulatory electrocardiographic (ECG) recorders (Holter monitors) for 24 hours during a work day. The authors found no effects of MC on the ECG tracings of any of the men observed, even when COHb was measured at levels in which adverse effects were observed in angina patients under controlled laboratory conditions. The usefulness of the study is limited because, although efforts were made to include men with heart disease, only 3 of the 24 monitored were known to have heart disease. Also, the day to day variability of ECG responses within an individual is very high. Much more data must be collected to establish the existence or absence of a cardiac response to MC among individuals with silent or symptomatic heart disease.

*c. Summary of cardiac toxicity.* In summary, although the animal studies and epidemiological data are non-positive for a cardiac effect due to MC exposure, the collected case reports are highly suggestive of an effect of MC on the subpopulation with symptomatic or silent heart disease. The special susceptibility of this subpopulation to cardiac stress resulting from the metabolism of MC to CO would be very difficult to detect in an epidemiological study unless very large populations were used or the segment of the population with heart disease was identified. OSHA feels that there is sufficient evidence of cardiac toxicity from exposure to MC and/or its metabolites that OSHA should protect the population at risk from COHb levels due to MC metabolism as low as 3%.

### 3. Hepatic Toxicity

*a. Animal studies—i. Acute studies.* Acute studies of MC exposure and liver toxicity have failed to demonstrate severe liver toxicity even at lethal or near-lethal doses. Kutob et al. (Ex. 7-27) and Klaassen et al. (Ex. 7-28) conducted investigations into the relationship between narcosis produced by single exposures to halogenated methanes and hepatotoxicity. In both cases MC was determined to be the least hepatotoxic of the halogenated methanes examined. In fact, MC produced no hepatotoxic effects by the parameters measured in the studies (bromsulphophthalein retention, SGPT activity and

histopathologic changes). The only injury described was a mild inflammatory response associated with lethal MC concentrations.

Short-term, nonlethal exposures to MC also seem to elicit minimal liver toxicity. A study by Weinstein et al. (Ex. 7-181) examined the effects of continuous inhalation exposures of female mice to MC for up to 7 days. Mild, nonlethal injury to the livers was noted by the authors, characterized by balloon degeneration of the rough endoplasmic reticulum (RER), transient severe triglyceride accumulation (fatty liver), partial inhibition of protein synthesis and breakdown of polysomes into individual ribosomes. The injury is similar to a mild form of carbon tetrachloride toxicity (a structural analog of MC) and suggests that although the toxicity due to MC is not as severe as that produced by carbon tetrachloride, the mechanism of toxicity may be similar. An interesting aspect to this study is that by seven days the animals appeared to be adapting to the exposure conditions: the fatty accumulation and ballooning RER was largely reversed and the animals were more active, more like control animals than at the start of the experiment.

*ii. Subchronic studies.* Subchronic exposures to MC produce more defined hepatic injury than that described as resulting from acute exposure to MC. MacEwen et al. (Ex. 7-14) studied the effects of continuous exposure of mice, rats, dogs and rhesus monkeys to 1000 and 5000 ppm MC for up to 14 weeks. Fatty liver, icterus, elevated SGPT and ICDH were reported in dogs at both concentrations, these effects appeared at 6-7 weeks of exposure to 1000 ppm MC and at 3 weeks of exposure to 5000 ppm. Monkeys were less sensitive to hepatic injury, presenting no changes in liver enzymes and only mild to moderate liver changes at 5000 ppm MC. No liver alterations were detectable in monkeys exposed to 1000 ppm MC. Mice and rats developed liver toxicity at both exposure levels, characterized by increased hemosiderin pigment, cytoplasmic vacuolization, nuclear degeneration and changes in cellular organization.

*iii. Chronic studies.* Chronic hepatic effects associated with MC exposure were observed in lifetime bioassays in three rodent species. In the NTP, Burek, and Nitschke studies (Exs. 7-8, 7-151, 7-173), rats were exposed to inhalation concentrations of MC from 50 ppm to 4000 ppm. Hepatic effects were noted after chronic exposure to as low as 500 ppm. Hepatic injury in rats was characterized by increased fatty liver,



cytoplasmic vacuolization and an increased number of multinucleated hepatocytes. At the higher doses (greater than 1500 ppm), increased numbers of altered foci and hepatocellular necrosis became apparent. Serota et al. (Ex. 7-180) administered 5 to 250 mg MC/kg body weight in the drinking water. Hepatic toxicity similar to that found in the inhalation studies was reported at doses from 50 to 250 mg/kg.

The chronic hepatic effects of MC in mice were investigated in two bioassays: NTP (Ex. 7-8) and Serota et al. (Ex. 7-179). The NTP study exposed mice to inhaled MC concentrations of 2000 and 4000 ppm. MC produced cytologic degeneration in both male and female mice and increased incidence of hepatocellular adenomas and carcinomas. The carcinogenic effects of MC are described in greater detail in the section on carcinogenicity. In mice exposed to 50 to 250 mg/kg/d MC in drinking water, Serota et al. found treatment-related increases in the fat content of the liver. Although some proliferative hepatocellular lesions were identified in this study, they were distributed across all exposure groups. Hepatocellular tumor incidences were not elevated above historical control incidences.

In the hamster, Burek et al. (Ex. 7-151) found very minimal treatment related changes in the livers of the MC exposed animals after exposure to 500, 1500 or 3500 ppm MC. A dose-related increase in hemosiderin was found in male hamsters at 6 months and at 3500 ppm at 12 months. No other changes in liver physiology were reported.

*iv. Summary of animal studies of hepatotoxicity.* In summary, the acute effects of MC exposure on the livers of experimental animals in these studies were slight and appear to be reversible. However, long term exposure to MC, as in the chronic bioassays, lead to more severe and more permanent changes in liver physiology. In the case of mice in the NTP study, these changes included carcinogenesis. The studies described above demonstrate the susceptibility of the liver as a target organ for MC, especially after chronic administration.

*b. Human studies—i. Epidemiological studies.* In a cross-sectional analysis of the health of workers in an acetate fiber production plant in which workers were exposed to 140 to 475 ppm MC, Ott et al. (Ex. 4-33c) reported statistically significant increases in serum bilirubin and alanine aminotransferase (ALT) (also known as serum glutamic pyruvic transaminase (SGPT)) when compared with a reference group of industrial workers. The elevation in bilirubin

levels showed a dose-response relationship, but the ALT levels were not associated with MC exposure. The authors felt that the increase in ALT in MC-exposed workers could not be attributed to MC because a dose-response relationship was not demonstrated and, therefore, the increase in ALT between the exposed and reference populations could be disregarded as a sign of liver toxicity. The authors concluded that although bilirubin elevation may be interpreted as a sign of liver toxicity, this interpretation was not supported by alterations in other liver parameters. OSHA feels that ALT can not be disregarded as unrelated to MC exposure based on the lack of dose response within the exposure group. The high variability of this parameter and the low numbers of individuals within certain exposure subgroups (e.g. 10 men exposed at 280 ppm), makes a dose-response relationship difficult to ascertain. Although the evidence is not unequivocal, OSHA believes that the elevated bilirubin coupled with the elevated ALT values indicate suggestive evidence of a hepatotoxic response to MC exposure in this worker population.

In an update to the study described above, Cohen et al. (Ex. 7-75) found 4 cases of liver/biliary duct cancer in workers with more than 10 years of exposure to MC and after 20 years from first hire. Further description of this study can be found in the section on carcinogenicity.

In a 1968 study, Kuzelova et al. (Ex. 7-26) found no liver abnormalities in workers exposed to MC concentrations from 29 ppm to 4899 ppm, even when cases of acute neurotoxicity were identified. However, in a study aimed primarily at detecting neurological changes due to MC exposure, Hanke et al. (Ex. 7-195) identified hepatic toxicity in 4 of 14 floor tile setters examined. These workers were chronically exposed to MC at concentrations as high as 400 to 5300 ppm. The average tenure of employment of these workers was 7.7 years.

*ii. Case reports.* In addition to the cross-sectional analyses of worker morbidity described above (Exs. 4-33c and 7-26), the relationship of MC exposure and hepatotoxicity has been studied by analysis of case reports. Welch (Ex. 7-73) collected 144 case reports of clinical disease reported subsequent to occupational MC exposure. Quantitative exposure estimates for individuals were unreliable, but the presence of MC in the work environment was ascertained for each employee. The most prevalent findings in these case reports were CNS

symptoms, upper respiratory syndrome and alterations in liver enzymes. The alterations in liver enzymes were not consistent among individuals, but may be suggestive of a MC-associated hepatotoxic effect. One case of hepatitis of unknown etiology was identified. The case physician felt that the hepatitis was secondary to solvent exposure. The solvents to which this employee was exposed included MC, xylene and methylethyl ketone.

Analysis of cases of fatal and near-fatal human exposures (Exs. 7-18, 7-19), indicated no apparent alterations of liver function. Acute concentrations of MC which caused narcosis and even death were not associated with changes in liver enzymes. The primary cause of death in MC-induced fatalities appeared to be CNS depression, not hepatotoxicity.

*c. Summary of human hepatotoxicity.* In summary, the toxicity data from the animal studies and the limited data from human MC exposures appear to coincide. Acute, high doses (even fatal doses) of MC do not noticeably impair liver function, while chronic, lower exposures are associated with mild to moderate hepatotoxicity, well described in rodent studies and suggested by analysis of human data. MC also induces liver tumor formation in rodents. Further, there is suggestive evidence that liver and biliary tumors may be produced after chronic MC exposure in humans, as well.

#### 4. Reproductive Toxicity

It is difficult to determine the potential adverse teratogenic or reproductive effects due to MC exposure because of the limited availability of human and animal data. Studies (Ex. 4-5) using chicken embryos have indicated that MC disrupts embryogenesis in a dose-related manner. Since the application of MC to the air space of chicken embryos is not comparable to MC administration to animals with a placenta, the exposure effect seen in the chick embryos can only be considered as suggestive evidence that an effect may also occur in mammalian systems. The limited rodent data which have been collected do not demonstrate teratogenic effects as the result of maternal MC exposure.

Information on the effects of MC on human reproduction, gathered through case studies and limited epidemiological investigations, suggests that MC may be associated with decreased male fertility and increased spontaneous abortions among exposed females. These studies are limited by lack of exposure information and some deficits in study design, so that the reproductive,



teratogenic or developmental toxicity of MC to humans is still unclear.

*a. Animal studies.* The teratogenicity of inhaled MC has been studied in rats and mice. Although the studies showed that MC was not teratogenic in either rodent species, some maternal toxicity and minor skeletal defects and post-natal behavioral effects among offspring were observed (Exs. 7-20, 7-21, 7-22).

*i. Mouse study.* In 1975, Schwetz et al. (Ex. 7-21) conducted a study on Swiss Webster mice. Mice inhaled 1250 ppm MC for 7 hours/day, on days 6-15 of gestation. On day 18 of gestation, Caesarian sectioning of dams was performed. A statistically significant increase in mean maternal body weight (11-15%) was observed in dams exposed to 1250 ppm MC; however, food consumption was not measured. The only effect on fetal development associated with MC exposure was a statistically significant increase in the number of fetuses which contained a single extra center of ossification in the sternum. The incidence of gross anomalies observed in the MC-exposed fetuses was not significantly different from the control litters. Maternal COHb level during exposure reached 12.6%; however, 24 hours after the last exposure, COHb returned to control levels.

*ii. Rat studies.* In the same study by Schwetz et al. (Ex. 7-21), Sprague-Dawley rats were exposed to 1250 ppm MC via inhalation for 7 hours daily on days 6-15 of gestation. No MC-associated effects were observed in food consumption or maternal body weight. Among litters from MC-exposed dams, the incidence of lumbar ribs or spurs was significantly decreased when compared to controls, while the incidence of delayed ossification of sternebrae was significantly increased compared to controls. No increased incidence of gross anomalies were observed in the fetuses from exposed rats compared to fetuses from control litters. No MC-associated effects were observed on the average number of implantation sites per litter, litter size, the incidence of fetal resorptions, fetal sex ratios or fetal body measurements, in the 19 litters that were evaluated. As observed in the MC-exposed mice, there was significant elevation of the COHb level in the dams, but the level returned to control values within 24 hours of cessation of exposure.

In 1980, Hardin and Manson (Ex. 7-22) evaluated the effect of MC exposure in Long-Evans rats after inhalation of 4500 ppm for 6 hours/day, 7 days/week prior to and during gestation. Four exposure groups were described. The first group was exposed to MC for 12 to 14 days

prior to gestation and during the first 17 days of pregnancy. The second group was exposed to MC only during the 12 to 14 days prior to gestation. The third group was exposed to MC only during the first 17 days of pregnancy. The fourth group (control group) was exposed only to filtered air. The purpose of this study was to test whether MC exposure prior to and/or during gestation was more detrimental to reproductive outcome in female rats than exposure during gestation alone.

In rats exposed to MC during gestation, there were signs of maternal toxicity, characterized by a statistically significant increase in maternal liver weights. The only fetal MC effects observed were statistically significant decreases in mean fetal body weights. No significantly increased incidence of skeletal or soft tissue anomalies was observed in the offspring.

In 1980, Bornschein et al. (Ex. 7-224) tested some of the offspring of the Long-Evans rats from Hardin and Manson's study described above. All four treatment groups were used to assess the postnatal toxicity of MC exposure at 4500 ppm. The general activity measurements of groups of 5-day old pups showed no exposure-related effects. At 10 days of age, however, significant MC-associated effects were observed in both sexes in the general activity test. These effects were still apparent in male rats at 150-days of age. This study showed that maternal exposure to MC prior to and/or during pregnancy altered the manner in which the offspring react and adapt to novel test environments at up to 150-days of age. These effects suggest that MC exposure prior to, or during pregnancy may influence the processes of orientation, reactivity, and/or behavioral habituation. No changes in growth rate, long-term food and water consumption, wheel running activity or avoidance learning were reported.

*b. Human studies.* Limited data have been collected on the reproductive effects of MC in male workers. In a study reported in the Occupational Safety and Health Reporter (Ex. 7-43), a greater risk of male sterility was found in male workers exposed to MC. In 1988, Kelly (Ex. 7-165) reported 4 cases of oligospermia in MC-exposed workers. The individuals involved in this study were employed at an automobile paint and body shop, and were part of a group of 86 workers who were interviewed for possible health effects resulting from MC exposure. Between Dec. 7, 1984 and June, 1986, 34 men with MC exposure and some health problems, were evaluated. The most prevalent complaints from these men were

associated with CNS dysfunction. Eight of the 34 men complained of genital pain. Four of these eight men consented to semen evaluation. The occupational exposure to MC for the four cases involved dipping auto parts into an open container of MC without the use of protective gloves. None of these men were found to have a motile sperm count greater than 20 million/ml.

Eight weeks following the cessation of MC exposure, the individual with the highest sperm count showed some improvement. However, the number of motile sperm was still below 20 million. In two of the men examined, the sperm count had declined over a period of several months. It was also noted that none of the 4 individuals tested had had children since occupational exposure to MC had begun, although none of the men were using contraceptives. These findings are based on a very small number of cases and more research is necessary before conclusions can be drawn about the human male reproductive toxicity of MC.

The reproductive and developmental effects of MC due to exposure in female workers have also been studied. According to information reported by Vozovaya et al. (Ex. 7-16), detectable levels of MC were found in the blood, milk, embryonal, fetal and placental tissues of nursing women exposed to MC in a rubber product plant. In a different study, by Taskinen et al. (Ex. 7-199), increased rates of spontaneous abortions were observed in female pharmaceutical workers exposed to MC. Exposure data were not reported in this study and it is unclear what confounding factors or other chemical exposures were present. OSHA believes that more research is necessary in order to evaluate the potential effect of MC on pregnancy outcomes.

Other studies have documented the adverse reproductive effects of human exposures to the MC metabolite, CO. The EPA has reviewed the literature on the effects of maternal CO exposure on the development of the fetus in the Air Quality Criteria for Carbon Monoxide (Ex. 7-201). Very high maternal CO exposures have resulted in fetal or infant death or severe neurological impairment of the offspring. CO reduces the amount of oxygen available to the tissues. The developing fetus is very sensitive to these effects. According to Fechter et al. (Ex. 7-200), low levels of CO exposure in animals have been shown to adversely affect the fetus, producing CNS damage or reduced fetal growth. These effects suggest that pregnant women may be especially



sensitive to the toxic effects of MC through its metabolism to CO.

c. *Summary of reproductive effects.* Results obtained from studies using the chick embryo are suggestive that embryotoxic and teratogenic effects may occur in mammals, but these results cannot be directly applied to mammalian systems. The rodent studies described here have not demonstrated that MC is embryolethal or teratogenic. Minor skeletal defects and postnatal behavioral effects have been noted in these studies, but the significance of these effects in assessing human risk of reproductive hazards is unclear. The case studies showing oligospermia and the increased incidence of spontaneous abortion in MC-exposed female pharmaceutical workers is suggestive evidence that human exposure to MC may cause adverse reproductive health effects. There is also some concern that pregnant women exposed to MC may suffer from adverse reproductive effects associated with increased COHb, due to MC metabolism.

Currently it is not possible to quantify the reproductive and developmental effects of MC. Each of the animal studies only observed effects at a single exposure level and a no adverse effect level was not identified. The human studies do not contain enough information on exposure levels or confounding variables to permit generation of a reproductive or developmental risk assessment. Since the developmental effects observed in mice and rats were mild and occurred at exposures from 1250 to 4500 ppm, it is OSHA's belief that a 25 ppm PEL, developed on the basis of carcinogenic effects, would also be protective against the reproductive health effects described in these studies.

#### E. Conclusion.

OSHA's determination that MC is a potential occupational carcinogen was based primarily on the positive findings of chronic inhalation bioassays in rodents. MC was carcinogenic to mice of both sexes, producing lung and liver neoplasms. In rats, MC produced dose-related increases in mammary tumors and increases in the number of tumors per tumor-bearing rat. The evidence in rodents is supported by epidemiologic findings from cellulose triacetate fiber production workers. This epidemiologic study suggests an association between liver and biliary cancer and long term (greater than 10 years) exposure to MC. This evidence is further supported by the observation of liver toxicity in animals and humans subsequent to chronic exposure to MC (suggesting the liver as a target organ for MC) and the

findings of genotoxic activity of MC in bacterial and mammalian cell systems.

Acute neurotoxicity has been demonstrated in humans and animals at relatively low inhalation concentrations of MC. There is preliminary evidence in case reports of humans with chronic occupational exposure to MC and in experimental research in gerbils that chronic exposure to MC may cause an irreversible neurotoxicity.

Because of the metabolism of MC to CO, there is a concern about the potential for cardiac toxicity, especially in sensitive populations, such as smokers, persons with silent or symptomatic heart disease and pregnant women. OSHA believes that it is important to limit MC exposure so that COHb production does not exceed 3% for these workers.

In summary, findings in humans and experimental animals exposed to MC are indicative of damage to the genetic material (DNA). Evidence from *in vivo* studies in animals and humans shows that genotoxicity may be expressed as increased incidence of cancer in the adult. Other adverse health effects from MC exposure, suggested by existing evidence, are hepatotoxicity, potentially irreversible neurotoxicity and increased cardiac stress.

### VIII. Preliminary Quantitative Risk Assessment

#### A. Introduction

The United States Supreme Court, in the "benzene" decision, (*Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980)) has ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made that there is a significant risk of health impairment at existing permissible exposure levels and that issuance of a new standard will substantially reduce or eliminate that risk. The Court stated that "before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices" [488 U.S. 642]. The Court also stated "that the Act does limit the Secretary's power to requiring the elimination of significant risks" [488 U.S. 644].

Although the Court in the Cotton Dust case (*American Textile Manufacturers Institute v. Donovan*, 452 U.S. 490 (1981)) rejected the use of cost-benefit analysis in setting OSHA standards, it reaffirmed its previous position in "benzene" that a risk assessment is not only appropriate,

but also required to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.

#### B. Choice of Data Base

The determining factor in the decision to perform a quantitative risk assessment is the availability of suitable data for use in such an assessment. In the case of MC, OSHA has determined that data are available to quantify the cancer risk. OSHA's approach for this risk assessment was, as a first step, to perform a critical review of the health studies associating MC exposure and cancer. The purpose of such a critical evaluation is to determine whether exposure to the substance has caused cancer. The critical review also enables OSHA to select those studies that have potential for use in a quantitative risk assessment. OSHA has reviewed risk assessments performed by scientists outside of OSHA to determine if they are relevant to the occupational situation (EPA, Exs. 4-6 and 7-129; CPSC, Exs. 5-2 and 7-126; FDA, Ex. 6-1; ECETOC Ex. 10-39; Reitz and Anderson, Ex. 7-125). In order to obtain additional professional opinion on how the MC data should be used for quantitative risk assessment, OSHA contracted with K.S. Crump and Company through Meridian Research Inc. to perform an independent quantitative risk assessment (Exs. 12 and 7-127). OSHA has evaluated these risk assessments and has made its own preliminary estimates of cancer risk associated with MC exposure to workers. OSHA extrapolated the data from the two-year inhalation study on rats and mice performed by the National Toxicology Program (NTP) (Ex. 4-35) in an effort to quantify the lifetime excess risk of cancer to humans. OSHA chose lifetime exposure levels of 1, 10, 25, 50, 100, and 500 ppm as possible scenarios to examine. The following discussion summarizes the data and conclusions of OSHA's preliminary quantitative risk assessment.

#### C. Selection of the Most Appropriate Studies

OSHA examined several studies in order to select the most appropriate data for performing a quantitative risk assessment. These include studies in which the route of exposure was inhalation (Burek et al., Ex. 4-25,



Nitschke et al., Ex. 7-29, and the NTP, Ex. 4-35) and two studies in which the route of exposure was drinking water (National Coffee Association, Exs. 7-30, 7-31). Data sets selected from these

studies are listed in table 7. In order to ensure complete analysis of the data, all data sets which showed an elevated incidence of tumors in a MC-exposed group, compared to controls, were

analyzed, whether or not the elevation of tumor response was statistically significant.

TABLE 7.—INCIDENCE OF TUMORS IN MICE AND RATS INDUCED BY METHYLENE CHLORIDE

Data set	Doses		Tumor incidence <sup>2</sup>
	Experimental (ppm)	Adjusted (mg/kg/day) <sup>1</sup>	
1. NTP—Male Rats; Mammary Adenoma or Fibroadenoma	0	0	0/50
	1000	406.7	0/50
	2000	813.5	2/50
	4000	1627.0	5/50
2. NTP—Male Rats; Mammary or Subcutaneous Adenoma, Fibroadenoma, or Fibroma	0	0	1/50
	1000	406.7	1/50
	2000	813.5	4/50
	4000	1627.0	* 9/50
3. NTP—Female Rats; Mammary Adenoma or Fibroadenoma	0	0	5/50
	1000	623.1	11/50
	2000	1246.1	13/50
	4000	2492.3	* 23/50
4. NTP—Male Mice; Alveolar/Bronchiolar Adenoma	0	0	3/50
	2000	1857.9	* 19/50
	4000	3715.9	* 24/50
5. NTP—Male Mice; Alveolar/Bronchiolar Carcinoma	0	0	2/50
	2000	1857.9	* 10/50
	4000	3715.9	* 28/50
6. NTP—Male Mice; Alveolar/Bronchiolar Adenoma or Carcinoma	0	0	5/50
	2000	1857.9	* 27/50
	4000	3715.9	* 40/50
7. NTP—Male Mice; Hepatocellular Adenoma	0	0	10/50
	2000	1857.9	14/49
	4000	3715.9	14/49
8. NTP—Male Mice; Hepatocellular Carcinoma	0	0	13/50
	2000	1857.9	15/49
	4000	3715.9	* 26/49
9. NTP—Male Mice; Hepatocellular Adenoma or Carcinoma	0	0	22/50
	2000	1857.9	24/49
	4000	3715.9	* 33/49
10. NTP—Male Mice; Alveolar/Bronchiolar or Hepatocellular Carcinoma	0	0	15/50
	2000	1857.9	21/49
	4000	3715.9	* 39/49
11. NTP—Male Mice; Alveolar/Bronchiolar or Hepatocellular Adenoma or Carcinoma	0	0	27/50
	2000	1857.9	34/49
	4000	3715.9	* 45/49
12. NTP—Female Mice; Alveolar/Bronchiolar Adenoma	0	0	2/50
	2000	2051.0	* 23/48
	4000	4101.9	* 28/48
13. NTP—Female Mice; Alveolar/Bronchiolar Carcinoma	0	0	1/50
	2000	2051.0	* 13/48
	4000	4101.9	* 29/48
14. NTP—Female Mice; Alveolar/Bronchiolar Adenoma or Carcinoma	0	0	3/50
	2000	2051.0	* 30/48
	4000	4101.9	* 41/48
15. NTP—Female Mice; Hepatocellular Adenoma	0	0	2/50
	2000	2051.0	6/48
	4000	4101.9	* 22/48
16. NTP—Female Mice; Hepatocellular Carcinoma	0	0	1/50
	2000	2051.0	* 11/48
	4000	4101.9	* 32/48
17. NTP—Female Mice; Hepatocellular Adenoma or Carcinoma	0	0	3/50
	2000	2051.0	* 16/48
	4000	4101.9	* 40/48
18. NTP—Female Mice; Alveolar/Bronchiolar or Hepatocellular Carcinoma	0	0	1/50
	2000	2051.0	* 21/48
	4000	4101.9	* 43/47
19. NTP—Female Mice; Alveolar/Bronchiolar or Hepatocellular Adenoma or Carcinoma	0	0	5/50
	2000	2051.0	* 36/48
	4000	4101.9	* 46/47
20. Burek—Male Rats; Salivary Gland Region Sarcoma	0	0	1/95
	500	147.4	0/95
	1500	442.3	5/95
	3500	1032.0	* 11/97
21. Burek—Female Hamster; Lymphosarcoma	0	0	1/91
	500	97.4	6/92
	1500	292.2	3/91
	3500	681.7	8/91
22. Nitschke—Female Rats; Mammary Adenoma, Fibroadenoma or Fibroma	0	0	52/70



TABLE 7.—INCIDENCE OF TUMORS IN MICE AND RATS INDUCED BY METHYLENE CHLORIDE—Continued

Data set	Doses		Tumor incidence <sup>2</sup>
	Experimental (ppm)	Adjusted (mg/kg/day) <sup>1</sup>	
23. NCA—Female Rats; Neoplastic Nodules .....	50	22.6	58/70
	200	90.2	81/70
	500	225.6	55/70
		0	0/98
		6.5	1/48
24. NCA—Female Rats; Pituitary Adenoma .....		58.3	2/49
		135.6	1/49
		262.8	* 3/47
		0	38/98
		6.5	16/48
25. NCA—Male Mice; Hepatocellular Hemangioma .....		58.3	11/49
		135.6	11/49
		262.8	28/47
		0	0/125
		60.6	1/200
26. NCA—Male Mice; Hepatocellular Adenoma or Carcinoma .....		123.6	2/100
		177.4	4/99
		234.3	0/125
		0	24/125
		60.6	51/200
		123.6	30/100
		177.4	31/99
		234.3	35/125

<sup>1</sup> For inhalation studies, adjusted dose was calculated as  $d(\text{mg/kg/day}) = d(\text{ppm}) \times (1.2 \times \text{mol. wt./mol. wt. of air}) \times \text{breathing rate} \times \text{hrs. of exposure}/24 \times \text{days of exposure}/7 \div \text{body wt.}$

<sup>2</sup> Incidence expressed as number of animals with response per number of animals examined for the response.

\* Statistically significant, using Fischer's Exact Test and a Bonferroni correction, at the .05/r level, where r is the number of test doses. For data sets 22–26 a Chi-square approximation of the Fischer Exact Test is used due to large sample size.

In a bioassay performed by the NTP (Ex. 4–35), eight-week old F344/N rats and nine-week old B6C3F<sub>1</sub> mice were exposed by inhalation to various concentrations of MC. Groups of 50 rats of each sex were exposed to MC at concentrations of 0, 1000, 2000, or 4000 ppm, while groups of 50 mice of each sex were exposed to concentrations of 0, 2000, or 4000 ppm MC. The inhalation exposures were administered 6 hours a day, 5 days a week for 102 weeks. Food was provided to the animals ad libitum except during the exposure periods, while water was available at all times via an automatic watering system. All animals were observed twice a day for mortality and moribund animals were sacrificed. Clinical examinations were performed once a week for 3.5 months, then twice a month for 4.5 months, and once a month thereafter. Each animal was also weighed weekly for 12 weeks, then monthly until the conclusion of the study at 104 weeks. All animals were necropsied and histologically examined. Three different neoplastic lesions were observed to have significantly increased incidence over the controls: mammary gland fibroadenomas and fibromas in male and female rats, adenomas and carcinomas of the lung in male and female mice, and adenomas and carcinomas of the liver in male and female mice.

In a two-year inhalation study by Burek et al. (Ex. 4–25), Sprague-Dawley

rats and Syrian Golden hamsters were exposed to MC six hours a day, five days per week for the length of the experiment. All animals were approximately eight weeks old at the start of the experiment. For the chronic toxicity and oncogenicity portion of the study, approximately 95 animals per sex of each species were assigned to each dose group. Dosage levels administered were 0, 500, 1500 or 3500 ppm MC. Additional animals were used for cytogenetic studies and interim sacrifices. Interim sacrifices occurred at 6, 12, 15, and 18 months with 5 to 10 animals of each sex sacrificed per dose group. Food was provided to the animals ad libitum only during non-exposure periods, while water was provided ad libitum at all times.

All animals were observed five days per week for general health, signs of toxicity, and mortality. Animals were sacrificed when moribund. Beginning in the third month of the study, all rats and hamsters were examined monthly for palpable masses. This procedure was continued for the duration of the study.

The final sacrifice was performed 24 months after the first exposure. All animals were necropsied and tissues were fixed in 10% formalin. The authors state that "conventional methods" were used for sectioning and staining "representative organs and tissues."

The only significantly increased response observed was the incidence of

sarcomas in the salivary gland region in high-dose male rats. This tumor response was not observed in other rat bioassays using the Fischer 344 rat at similar doses or the Sprague-Dawley rat at lower doses. The authors state that the salivary gland tumors may have been affected by the presence of a common viral disease, sialodacryoadenitis, which primarily affects the salivary glands. However it should be noted that no sarcomas were detected in females similarly affected with this virus. Female hamsters showed an increase in lymphosarcomas in the lymphoreticular system. However, high dose females had greater survival than controls, such that after correcting for this difference the authors did not feel this response was significant.

In a two-year inhalation study, by Nitschke et al., (Ex. 7–29) male and female Sprague-Dawley rats were exposed to 0, 50, 200, or 500 ppm MC for 6 hours/day, 5 days/week for 20 months for male rats and 24 months for female. One group of female rats was exposed to 500 ppm MC for the first 12 months of the study only, while another group of female rats was exposed to 500 ppm for the last 12 months of the study (designated 500:0 and 0:500, respectively). Animals were distributed into groups of 185 animals per sex per group for the 0 and 500 ppm dose groups and 90 animals per sex per group for the 50 and 200 ppm dose groups. The 500:0



and 0:500 ppm dose groups consisted of 30 female rats each. Eighteen additional female rats were included in each exposure group for determining the rate of DNA synthesis in the liver. Five rats from each sex/dose group were sacrificed after 6, 12, 15, and 18 months of exposure.

Food and water were provided to the animals *ad libitum* except during exposure periods. Body weights were determined at the initiation of the study, twice a month for the first three months, and monthly thereafter. Animals were observed daily after the exposures for signs of toxicity and changes in appearance, and dead and moribund animals were removed.

The authors state that, "conventional methods" were used for processing representative sections of organs and tissues that were histologically examined. All animals from the interim and terminal sacrifices were subjected to complete examinations. Some of the animals that died spontaneously or were sacrificed when moribund did not receive complete examinations. The only significantly increased response in this study was the increased incidence of benign mammary tumors in the female rats at the 200 ppm dose.

In a study sponsored by the National Coffee Association (NCA) (Serota et al.; Exs. 7-30 and 7-180), MC was administered to eight-week old Fischer 344 rats via the drinking water. MC was added to deionized water to provide target doses of 5, 50, 125, or 250 mg MC/kg body weight/day. Rats were randomly assigned to treatment groups with 85 animals in each treated group, while the controls consisted of 135 animals. An additional treatment group ("recovery" group) of 25 animals received a target dose of 250 mg/kg/day for the first 78 weeks of the experiment, and then received deionized water alone until terminal sacrifice. Actual doses received by the rats were measured (by measuring water consumption) and the mean daily consumption of MC was reported for each dose group. The male rats received average daily doses of 5.85, 52.28, 125.04, 235.00 or 232.13 mg/kg/day. The female rats consumed an average of 6.47, 58.32, 135.59, 262.81, or 268.72 mg/kg/day.

Food and water were provided to the animals *ad libitum*. Observations for mortality and signs of moribundity were performed twice daily for the first 52 weeks. Thereafter, a third observation was performed five days a week in addition to the twice daily observations. All animals that were found moribund were sacrificed. Body weight, clinical signs, and food consumption were measured weekly, while water

consumption was measured twice weekly. Interim sacrifices were performed on 5, 10, or 20 animals per group at 26, 52, and 78 weeks. These animals were excluded from subsequent analysis, as were the recovery groups. All surviving animals were sacrificed after 104 weeks on the study. A complete necropsy was performed on every animal, whether found dead, sacrificed when moribund, or sacrificed at the end of the study.

For the male rats, the incidence of tumors (of any type) in the treatment groups at any dose level was not significantly increased over the controls. The female treated rats showed a marginally significant increased incidence of neoplastic nodules and pituitary adenomas when compared to the controls. Increased incidence of mammary tumors in female rats were not observed in this study. The dosages were, however, 10-fold less than those in the NTP study.

In the second 24-month oncogenicity study by the NCA (Serota et al.; Exs. 7-31 and 7-179), MC was administered to eight-week-old B6C3F<sub>1</sub> mice in the drinking water. The mice were divided into four dose groups and two control groups of various sizes. (Since the control groups were treated identically, data for the two groups were combined.) MC was mixed with drinking water to provide doses of 60 mg/kg/day (200 males and 100 females), 125 mg/kg/day (100 males and 50 females), 185 mg/kg/day (100 males and 50 females), and 250 mg/kg/day (125 males and 50 females). The control groups consisted of 125 males and 100 females. Actual doses received by the mice were measured and the mean daily consumption of MC was reported for each group. The male mice received average daily doses of 60.55, 123.61, 177.45, or 234.29 mg/kg/day. The female mice received average daily doses of 59.46, 118.19, 172.41, or 237.76 mg/kg/day.

Food and water were provided to the animals *ad libitum*. Observation for mortality and signs of moribundity were performed twice daily for the first 52 weeks. All animals that were found moribund were killed. Body weights, clinical signs, and food consumption were measured weekly, while water consumption was measured twice weekly. All surviving animals were sacrificed after 104 weeks on the study. A complete necropsy was performed on every animal, whether found dead, sacrificed when moribund, or sacrificed at the end of the study. Histopathological examination of the livers, eyes and palpable or suspected neoplasms were performed on the low- and mid-dose groups. Animals in the

control and high-dose groups received complete histopathological examinations.

For the female mice, the incidence of tumors (of any type) in the treatment groups was not significantly increased over the controls at any dose level. In male mice, the incidence of hemangioma of the liver and hepatocellular adenoma or carcinoma were significantly increased over the incidence in controls for the 185 mg/kg/day dose group only. Incidence in the high dose group for either response was not significantly different from controls.

Of the animal studies evaluated, the Crump report concludes that the NTP study provides the clearest evidence of the carcinogenicity of MC from both a toxicological and statistical standpoint. The report states that, in the NTP study, MC induced significant increases in benign mammary tumors in male and female rats and alveolar/bronchiolar and hepatocellular neoplasms in male and female mice. In contrast, the increases in the incidences of salivary gland sarcomas in rats and lymphosarcomas in hamsters observed in the Burek study were of questionable significance and the statistically significant responses observed in the Nitschke study were observed only at a mid-level dose group. No dose-related effect on the incidence of liver tumors in female mice or of lung tumors in either sex was observed in the NCA study. However, the highest dose tested in the NCA study was more than ten times less than that administered in the NTP study; therefore, the delivered dose to the tissue sites was lower. These lower doses administered in the drinking water may have been further reduced by biotransformation during first passage through the liver or elimination before reaching the target tissues, especially the lungs. Lower doses result in fewer tumors and lower statistical power of the study. In addition, the oral route of exposure in the NCA studies differs from the route of exposure typical to workers in the occupational setting.

The EPA, the CPSC and the FDA have also chosen the NTP study as the most appropriate data for their quantitative risk assessments because of the quality and clear positive responses observed in the bioassay. OSHA agrees with these reasonings and supports the use of the NTP bioassay for the best estimate of risk.

OSHA has also reviewed three human studies (Exs. 8-14c, 7-75, 4-33 and 7-163) which examined the possible relationship between MC exposure and cancer. Friedlander et al. studied mortality in the film coatings operations



of a Kodak film plant using a cohort of 1,013 men employed in film coating operations at any time between January, 1964 and December, 1970 and who had at least one year of employment in that department. Cohort members were followed through 1988. The control groups were defined as the male population of New York State living outside New York City (NYS) and an industrial control group of 40,000 male employees (not employed in the roll coating division) of Kodak Park, Rochester, New York (KP). These groups were used to calculate expected numbers of deaths. A total of 55 malignant neoplasms were observed in the cohort versus 79 and 75 expected in the NYS and KP comparison groups, respectively. Eighteen lung cancers were observed whereas 25.6 (NYS) and 22.8 (KP) were expected; 18 digestive system neoplasms occurred (22.6 (NYS) and 21.7 (KP) expected) and 8 pancreatic cancers occurred (4.2 expected in both NYS and KP control groups). In previous analyses of this cohort, the authors stated that the observed pancreatic cancers were suggestive of an increase in malignancy, although the *p* value was not considered statistically significant for a non-hypothesized cause of death. However, in the latest update (Ex. 7-163), which followed the cohort through 1988, the incidence of pancreatic cancer no longer approached statistical significance when compared with control values (*p*=0.13). The authors believe, and OSHA agrees, that this evidence does not indicate an association between pancreatic cancer and MC exposure. However, future updates of this cohort will be assessed for effects on the pancreas, as well as other organs.

Ott et al. (Ex. 4-33) identified a plant which had used MC as a solvent in the production of cellulose triacetate fibers since 1954 and a second plant that had similar production characteristics but did not use MC. The cohort studied consisted of employees who worked at least three months in the preparation or extrusion areas of either plant between 1954 and 1977. A total of 1271 MC-exposed and 948 control workers were identified. Follow-up extended through June 1977. Among the white male or female employees, 7 malignant neoplasms were observed in the exposed group (11.5 expected on the basis of U.S. national rates) and 7 were found in the control group (12.3 expected). There was no discussion by the authors of the types of malignancies observed and the associated expected numbers of such deaths, because of the small numbers of malignancies identified in this cohort. MC-exposed

and control workers came into contact with acetone and had other minor chemical exposures.

An update of this study by Cohen et al. (Ex. 8-14c) extended the follow-up for this population through September 1986. Twenty-eight deaths from malignant neoplasms were observed versus 33 expected (US general population and York County, S.C. death rates were used as the comparison). The most significant results were the four deaths from liver/biliary cancers reported versus 0.53 and 0.86 cancers expected (US and York County statistics, respectively). Seven cancers were found in the digestive organs, versus 7.05 (US) and 6.76 (York County) expected. One cancer of the pancreas was reported compared to 1.4 (US) and 1.53 (York County) expected. In cancers of the respiratory system, 8 were found versus 9.56 and 10.37 expected (US, York County).

In addition, the National Paint and Coatings Association has submitted an epidemiological study by SRI (Ex. 10-29b) of 16,243 workers in paint and varnish manufacture. No statistically significant excess cause-specific mortality was identified in this cohort or the subcohort of 238 tub and tank cleaners presumed to have the highest MC exposures. There was no documentation of individual or job category exposure data, although typical exposure to MC was described as less than 100 ppm. In addition, workers in this study were exposed to multiple chemicals in the production of paint and varnish. Overall, because of the lack of exposure data and possible confounding exposures, this study had little power to identify an association between MC exposure and cause-specific mortality.

The Ott, Friedlander and NPCA studies have been interpreted as non-positive. However, the Cohen update is suggestive of a positive carcinogenic response to MC exposure. The data from the Cohen update and that from the Friedlander study can be used to derive upper confidence limits on human risk. The use of non-positive epidemiological studies is supported by the Office of Science Technology and Policy (OSTP) which states that "The lack of evidence of a hazard from an epidemiological investigation can also be useful in that within the scope of the study, a likely range can be determined for estimates of risk" (50 FR 10371). The EPA and K.S. Crump and Company also use this approach in their risk assessments. Therefore, since the use of these studies may provide additional information as to the range of possible human risk, OSHA feels it is reasonable and

appropriate to include analysis of this type in the preliminary quantitative risk assessment.

#### *D. Selection of Data Sets*

Data sets from the animal studies selected in the Crump report (Ex. 12) for subsequent quantitative analysis are listed in table 7. These data sets represent positive responses observed in the various studies. From these studies, as stated previously, the NTP study was selected as the most appropriate study for quantitative analysis. From the NTP study certain data sets are considered more appropriate than others. For example, results from mouse alveolar/bronchiolar adenomas or carcinomas in male or female mice were chosen in the Crump report as the most appropriate data sets for the following reasons:

1. Alveolar/bronchiolar tissues appear to be more sensitive to the carcinogenic effects of MC than other mouse tissues;
2. Males and females show a consistent response, with females slightly more sensitive;
3. Mice have a relatively low background incidence of alveolar/bronchiolar neoplasms in either sex; and
4. The relevance of mouse liver tumors in assessing carcinogenic risk to humans has been questioned by some investigators.

The EPA, the CPSC and the FDA chose to use the data sets for combined responses of adenomas and carcinomas of the lung and liver. Specifically, the EPA placed emphasis on the experimental species and sex group showing the highest risk: lung/liver adenomas or carcinomas in female mice. The CPSC used mammary, lung and liver benign and malignant responses and averages male and female estimates and lung and liver estimates to derive combined response risk estimates. The FDA used benign and malignant responses of female mice. The Crump report noted that it may be reasonable to combine lung and liver responses to give an indication of MC's potency, due to the fact that metabolism of MC occurs by the same pathway in both lung and liver and thus results in the same ultimate metabolites. However, the report adds that since both tissues have different background responses, combining responses may tend to affect risk estimates. The results from combining responses are discussed later.

At this time OSHA believes it may be more appropriate to consider different tissue sites separately rather than combining them and to focus on



alveolar/bronchiolar tumors, as this appears to be the more sensitive site.

The adenomas are included in the quantitative analysis because OSHA holds that the presence of benign tumors should be interpreted as representing a potentially carcinogenic response for this case. This belief is supported by the OSTP's views on chemical carcinogenesis (50 FR 10371). They state that at certain tissue sites, such as the lung, most tumors diagnosed as benign really represent a stage in the progression to malignancy. Therefore, it is appropriate and sometimes necessary to combine certain benign tumors with malignant ones occurring in the same tissue and the same organ site. They also state that "the judgement of the pathologist as to whether the lesion is an adenoma or an adenocarcinoma is so subjective that it is essential they be combined for statistical purposes." (50 FR 10371). Additionally, the EPA, the CPSC and the FDA have also included benign responses in their assessments.

#### *E. Statistical Methods and Predictions*

##### **1. Choice of Model**

Because of the complexity of the carcinogenic process and the fact that so little is understood about the pathogenesis of cancer, there is uncertainty in describing the shape of the dose response curve for carcinogens when data from high doses are used to predict risk at low dose. In general, there are usually no data points in the low dose region to aid in defining the curve. Hence investigators often turn to mathematical models in an attempt to describe the relationship between dose and response at low doses.

There are several types of models generally employed, among which are the one-hit, probit, multi-hit, Weibull and multistage models. OSHA has consistently shown a preference for the multistage model of carcinogenesis. This model is based on the theory that carcinogens induce cancer through a series of stages. EPA, in its guidelines for carcinogen risk assessment (51 FR 33992), also stated a preference for the multistage model due to the fact that it incorporates the current scientific opinion on carcinogenesis. Specifically, for MC the EPA and the CPSC used the

multistage model in their quantitative risk assessments. EPA stated that, in addition to the biological plausibility of the multistage model, the preliminary mutagenic data support the use of a linear low dose model. The CPSC justified its use of the multistage model based on their observations that other models have shown no more than a 3-fold variation in risk estimates for MC and they provide little refinement in predicted risks compared to the multistage model. Likewise K.S. Crump and Company, in their risk assessment for OSHA, used an updated version of GLOBAL82, a computer program based on the multistage model, to produce risk estimates for cancer. Additional analyses of the use of other models and the incorporation of pharmacokinetic modeling and the effect on the predicted risk are discussed later.

##### **2. Species to Species Extrapolation**

Using animal data to estimate human risk requires extrapolation between species. The best agreement between observed and predicted human cancer risk is often obtained when experimental doses are scaled to "human equivalent doses" using either ppm in air, mg/kg/day or mg/m<sup>3</sup>/day (OSTP, 50 FR 10371). A ppm in air dosage scale is generally used when site-of-contact tumors are involved, which is not the case for MC. The lung in this case is not considered a site-of-contact tumor because it is believed that in the lung, as in the liver, carcinogenicity may be a result of metabolism of MC. For non-site-of-contact tumors there is no conclusive evidence as to whether it is more appropriate to use a body weight basis (mg/kg/day) or a surface area basis (mg/m<sup>2</sup>/day) to calculate dose equivalency. The dosage scale used will affect the magnitude of the projected risk. For example, calculating dose equivalency on a body weight basis rather than a surface area basis can reduce the estimated human risk by approximately 6-fold when rat data are used for modeling human response and up to 14-fold for mouse data.

The EPA chooses the more conservative basis for extrapolation, the relative surface area. Likewise, the

CPSC uses the mg/m<sup>2</sup>/day due to the theoretical basis that chemicals are more slowly metabolized and eliminated on a weight basis in larger species. However, K.S. Crump and Company and the FDA use mg/kg/day dose equivalency in their risk assessments.

Based on the lack of information to support one dosage scale over another and the fact that OSHA has used the mg/kg/day in other risk assessments (i.e. ethylene oxide), OSHA has used the mg/kg/day dosage scale for MC.

##### **3. Prediction of Risk**

K.S. Crump and Company's predictions of risk for cancer, based on selected data sets from the NTP bioassay, are presented in table 8. The predictions of risk are based on a worker's lifetime exposure scenario of 8 hours per day, 5 days per week, 50 weeks per year for 1 and 45 years. Predictions of risk from the selected data sets are listed separately, and can be used to formulate a range of predicted risk. As shown in table 8, the multistage model predicts a lifetime excess risk MLE of cancer from occupational exposure to MC at the current PEL of 500 ppm as 33.2 per 1000 workers, based on the male mice lungs tumors. The female mice data predict an excess risk MLE of 45.5 per 1000 workers at 500 ppm for 45 years. OSHA has used these data to formulate a range of predicted excess risk of 33.2 to 45.5 per 1000 at 500 ppm for 45 years. The 95% upper confidence limits associated with the MLE's for this exposure level are 49.9 to 57.7 deaths per 1000 workers. Upper confidence limits are useful in assessing the amount of statistical variation found in the data being used for the quantitative risk assessment. The excess risk of cancer from an occupational exposure of 25 ppm ranges from 1.67 to 2.32 per 1000 workers with upper confidence limits of 2.56 to 2.97 per 1000 workers. A reduction in the PEL from 500 ppm to 25 ppm would constitute a 95% reduction in the estimated risk. Chi-squared goodness of fit test results are given in order to judge the fit of a given model to the data. The closer the p-value associated with a chi-square goodness of fit statistic is to one, the better the fit.



TABLE 8.—ESTIMATES OF EXTRA RISK PER 1000 WORKERS BASED ON INHALATION DATA SETS, BY INTENSITY AND DURATION OF EXPOSURE <sup>1</sup>

Data set	Methylene chloride concentration (ppm)	MLE <sup>3</sup> years of exposure		95% Upper limit years of exposure	
		1	45	1	45
NTP—Male Mice; <sup>2</sup> Alveolar/Bronchiolar Adenoma or Carcinoma.....	1	0.00149	0.0669	0.00228	0.109
	10	0.0149	0.669	0.0228	1.09
	25	0.0372	1.67	0.0569	2.56
	50	0.0743	3.34	0.114	5.11
	100	0.149	6.68	0.228	10.2
	500	0.743	33.2	1.14	49.9
NTP—Female Mice; <sup>2</sup> Alveolar/ Bronchiolar Adenoma or Carcinoma.....	1	0.00207	0.0930	0.00264	0.119
	10	0.0207	0.930	0.0264	1.19
	25	0.0517	2.32	0.0660	2.97
	50	0.103	4.64	0.132	5.92
	100	0.207	9.26	0.264	11.8
	500	1.03	45.5	1.21	57.7

<sup>1</sup> From multistage model. Extra risk  $[P_E = (P(d) - P(o))/1 - P(o)]$ . Adjusted doses were used.<sup>2</sup> Chi square goodness of fit and associated p-value is <.0001 and 1.00 respectively.<sup>3</sup> Maximum likelihood estimate.

### F. Other Models

In addition to the multistage model, K.S. Crump and Company also implemented the multistage-Weibull time-to-tumor model to analyze the selected data sets. This extension of the multistage model estimates the probability of occurrence of a tumor by the time selected rather than the probability of death from tumor. The

model was implemented by using the computer program WEIBULL82. In these analyses, tumors are assumed to be incidental and time is set equal to the length of the experiment.

Table 9 compares predicted average daily dose of MC which would give a fixed risk of 1 per 1000, based on the results of the multistage-Weibull time-to-tumor model and the multistage model. In each case, the estimates in the

multistage-Weibull model are similar to those predicted by the multistage model, differing by less than an order of magnitude. The results derived from the multistage-Weibull model are not consistently lower than those from the multistage model, and in several cases, result in lower bound estimates of dose that are higher than the multistage model estimates.

TABLE 9.—ESTIMATES OF AVERAGE DAILY DOSES OF METHYLENE CHLORIDE (MG/KG/DAY) CORRESPONDING TO AN EXTRA RISK OF  $10^{-3}$  FOR INHALATION DATA SETS, <sup>a</sup> by Model

Data set	Model			
	Multistage model		Multistage-Weibull <sup>b</sup>	
	95% Lower limit <sup>c</sup>	MLE	95% Lower limit <sup>c</sup>	MLE
NTP—Male Mice; Alveolar/Bronchiolar Carcinoma.....	6.60	13.4	6.46	92.4
NTP—Female Mice; Alveolar/Bronchiolar Carcinoma.....	4.41	14.7	4.97	10.3
NTP—Male Mice; Alveolar/Bronchiolar Adenoma or Carcinoma.....	2.06	3.15	1.56	53.6
NTP—Female Mice; Alveolar/Bronchiolar Adenoma or Carcinoma.....	1.77	2.26	1.31	11.1
NTP—Male Mice; Alveolar/Bronchiolar or Hepatocellular Adenoma or Carcinoma.....	2.16	89.7	1.27	54.4
NTP—Female Mice; Alveolar/Bronchiolar or Hepatocellular Adenoma or Carcinoma.....	1.18	2.97	1.37	46.0
NTP—Male Rats; Mammary Adenoma or Fibroadenoma.....	13.1	154	5.95	119
NTP—Male Rats; Mammary or Subcutaneous Adenoma, Fibroadenoma or Fibroma.....	7.53	106	18.4	171
NTP—Female Rats; Mammary Adenoma or Fibroadenoma.....	3.66	5.95	2.29	4.05

<sup>a</sup> From the models fit to data in Table 7. The adjusted doses were used.<sup>b</sup> The estimates are calculated as of the end of the experiments from which the data is taken, i.e. 104 weeks.<sup>c</sup> These limits are one-tailed limits.

Data sets for alveolar/bronchiolar carcinoma in male and female mice, presented in Table 9, show the effect of combining benign and malignant tumors in the risk models. For alveolar/bronchiolar carcinomas and for alveolar/bronchiolar adenomas or carcinomas the average daily doses differ by less than an order of magnitude. Similarly, the estimates from combining alveolar/bronchiolar and hepatocellular adenomas or carcinomas

differ little between models and data sets. Also shown are data sets for benign mammary neoplasms in male and female rats. The lower limits derived from the rat bioassay data are consistent with the range of lower limits estimated from the mouse data sets.

In general, estimates of risk from the Weibull time-to-tumor model agreed with those from the multistage model. Thus, the estimates from the multistage model generally represent the level of

risk predicted by both models. The multistage model has an added advantage in that no assumption must be made as to whether tumors are incidental or fatal as is the case when using the time-to-tumor model with the NTP data, where no information on incidental or fatal tumor type was provided. Therefore, the multistage model is preferred for purposes of this risk assessment.



The predictions of risk for cancer based on the epidemiologic studies were estimated by K.S. Crump and Company who used a relative risk model and a life table approach. It was assumed that the observed cancers in dose group  $i$ ,  $O_i$ , were distributed as a Poisson random variable with mean  $E_i (1 + Bd_i)$ . Here  $E_i$  was the expected, background number of cancers and  $d_i$  was the cumulative exposure in group  $i$ . The potency parameter  $B$  and its 95% one-sided statistical confidence limits were estimated by likelihood methods. These parameters were used to estimate risk for different patterns of exposure. From the two occupational cohorts, in the Friedlander and Cohen studies, the 95% upper confidence limits on potency parameter estimates for lung cancers and total malignancies were all positive. Thus, despite the generally non-positive evidence provided by these studies, they were consistent with some positive effect of MC. In fact, the number of extra cancers expected from these upper bound estimates could be substantial. Using the Friedlander and Ott studies, in the case of total malignancies, for a 500 ppm exposure for 45 years, 241 to 334 extra cancer deaths per 1000 workers is estimated. Using the Friedlander study only, where data was included for lung cancer incidence, 179 extra lung cancers per 1000 workers exposed at 500 ppm over 45 years were estimated. It was estimated that 5 extra lung cancers would be expected per 1000 workers for a 25 ppm, 45 year occupational exposure to MC.

Thus, the epidemiological data were not inconsistent with the results from the bioassay analyses. This is true in the sense that the range of risks predicted on the basis of the epidemiology includes the risks extrapolated from the animal data. The animal results, specifically the lung and liver tumors, provided an estimate of the potency of MC for causing cancer and should not be understood to imply that lung and liver tumors are the only tumors that should be of concern in humans. Differences in metabolism, storage, and elimination between humans and rodents may entail different sites of action, but have no effect on the potency of the chemical. The direct human evidence is consistent with the potency estimates derived from the animal bioassay data.

#### G. Other Risk Assessments

The EPA Carcinogen Assessment Group (CAG) (Ex. 4-6) has presented a risk assessment for MC based on evidence from the NTP bioassays. CAG reported that the NTP study produced significant exposure-related increases in

tumor incidences, with the strongest evidence of carcinogenicity provided by mammary and subcutaneous tumors in rats and lung and liver tumors in mice. Data on these endpoints were analyzed by fitting the multistage model with one less stage than the number of doses, and by fitting the time-to-tumor response model. Risk was measured by extra risk and doses expressed in terms of mg/body-surface-area/day were assumed to be equivalent across species. For purposes of comparison, EPA also fit four Weibull and probit models and two other configurations of the multistage model to the data. EPA has also recently modified its risk assessment to incorporate pharmacokinetic considerations. Their approach as well as their criticisms of the pharmacokinetic model will be discussed later.

EPA concluded that the multistage model provided an adequate fit, that for rats the largest upper confidence limit on risk was produced by the data for mammary tumors in females, and that for mice the largest confidence limit was for females with either adenomas or carcinomas of the lung and/or liver. The EPA pointed out that there was high mortality in the mouse and female rat high dose groups, which may have resulted in underestimation of risks. Male rats experienced high mortality in all dose groups. NTP reported that the high mortality might be due to the frequent occurrence of leukemia in all groups. The largest risks were estimated for the combined carcinomas and adenomas of the lung and/or liver in female mice, so these data received emphasis in the analyses.

To adjust the data for early mortality, EPA eliminated from the data all deaths before the first observed tumor (week 61 of the study) and refit the multistage model. This did not result in large changes in upper confidence limits on extra risk, but did, in some cases, have a great effect on maximum likelihood estimates (not an uncommon phenomenon).

In their time-to-tumor analysis, EPA made assumptions as to whether tumors were fatal or incidental. The NTP pathologists did not provide information on whether specific tumors caused death. EPA analyzed the data for both incidental and fatal tumors and compared the results of the two time-to-response analyses with the quantal analysis. The slopes for the confidence limits of the quantal multistage model were all between or near the slopes for the confidence limits of the time-to-response models, and the analysis assuming that the tumors were

incidental produced higher slopes (and therefore risks) than the analysis assuming that the tumors were fatal.

Because time-to-response models have been less widely used, and because they require that assumptions be made as to the cause of death, EPA chose to use the quantal model for the final risk assessments.

EPA also fit the multistage model to data from the studies conducted by Burek, Nitschke and the NCA and compared the resulting risk estimates to those derived using the NTP experiments. Similar tissue sites were used in both cases. Upper limits on risk were generally in the same range as those produced by the NTP study data.

To estimate human risks from the NTP animal data, EPA used upper confidence limits on risk for female mice lung or liver adenomas or carcinomas. Using this information EPA additionally applied correction factors to account for differences in surface area and to correct for differences in dosing regimens between species in order to convert animal doses to equivalent human doses.

Based upon the female mice data, EPA predicted the extra risk to a human exposed to 1 ppm continuously for a lifetime as 0.014 (14 excess cancer cases per 1000 exposed). In this case, lifetime cancer risk was calculated assuming humans are exposed continuously over the entire course of their life. It was also assumed that humans breathe 20 m<sup>3</sup>/day. This approach is similar to that taken by the CPSC but differs from OSHA's approach, in which cancer risk is calculated based on a working lifetime and an inhalation rate of 9.8 m<sup>3</sup>/8-hour workday.

Using the upper confidence limits from the NTP female mice (liver and lung tumors), EPA calculated that in the non-positive epidemiological studies by Friedlander (Ex. 4-30), MC would cause an expected excess of 2.8 to 11.3 deaths in a cohort of 252 exposed workers. According to the EPA, the power of the study to detect 2.8 excess deaths was only 7%, and to detect 11.3 excess deaths was 51%. The EPA concluded that this study did not have the power to rule out an overall cancer risk and therefore the non-positive result of this epidemiological study is not inconsistent with the positive result of the NTP animal bioassay.

Hearne et al. (Ex. 4-96a), in response to EPA's analysis, calculated the upper confidence limits of risk for their cohort using improved MC exposure data and EPA's original risk assessment. Hearne et al. stated that the excess deaths expected in this cohort were 11 in the



high exposure subcohort of 252 and 35 deaths in the total cohort. Because of differences in the statistical analyses and refinement of the exposure data, the authors have determined that their epidemiological data had 81% and 91% power to detect the lung and liver excess cancers predicted by the animal model.

Tollefson et al. (Ex. 7-249), from the FDA, also compared the cancer risks predicted from the NTP bioassay with the Hearne epidemiologic evidence. The risk assessments used for comparison were those performed by EPA and FDA. Tollefson et al. concluded that the power of the Hearne study to predict excess lung and liver cancer deaths for the most recent update of the study cohort were 50% for the EPA upper 95% confidence limit lifetime potency and 10% if FDA's lifetime potency value was used. These values correspond to a relative risk of 1.4 for the EPA assessment and 1.01 for the FDA assessment. Since OSHA's estimate of risk is most similar to that calculated by FDA, it is clear that the expected increase in mortality in the total cohort from lung and liver cancer was unlikely to be detected in the cohort described by Hearne. Tollefson went on to calculate the expected increase in mortality from lung and liver cancer in this cohort if they were followed until the entire cohort had died. The risk assessment produced by EPA would predict that there would be 35.5 excess cancer deaths, yielding a 95% power to detect the excess. The FDA risk assessment, however, would only predict 1.1 excess deaths from lung and liver cancer in this cohort, or 10% power to detect the excess.

The CPSC has also performed a MC risk assessment (Ex. 5-2). CPSC used the NTP bioassay as its choice for the data on which to base its risk estimates. As with the EPA, the CPSC has also recently incorporated pharmacokinetics into their risk assessment and this will be discussed later. The endpoints selected for the final analyses were rat mammary fibroadenomas, mouse hepatocellular and alveolar/bronchiolar carcinomas and mouse hepatocellular and alveolar/bronchiolar adenomas and carcinomas. Data on these endpoints were analyzed using a variety of models to produce maximum likelihood estimates and lower confidence limits for the dose corresponding to a risk of  $1 \times 10^{-5}$ . In particular, the multistage model (with the number of stages not restricted by the number of doses), was selected over other models, maximum likelihood estimates were used rather than upper confidence limits and male

and female estimates were averaged rather than using the more sensitive; in each case the choice was justified by pointing out that the alternative would change the estimates by a factor of only about 2.

To extrapolate estimated risks from rodents to humans, the risk estimates from the multistage model, based on rodent data were multiplied by two correction factors, (mg/kg/day of MC inhaled by humans  $\div$  mg/kg/day of MC inhaled by rodents and (weight human/weight animal)<sup>1/3</sup>), to account for dose equivalency on a mg/m<sup>2</sup>-body-surface-area/day basis. Values were further adjusted to correct for the proportion of lifetime exposed; 6 hours a day at 5 days a week for 24 months. Risks at the combined sites were estimated by adding the risk estimates calculated independently at the two sites.

The final estimates derived for lifetime human continuous inhaled concentrations, producing a risk of  $10^{-5}$ , based upon benign responses in rats, malignant responses in mice and malignant plus benign responses in mice were, respectively, 0.012 ppm, 0.0033 ppm and 0.0012 ppm. For a lifetime inhalation of 1 ppm, the estimated lifetime human carcinogenic risks are .830 per 1000, 3 per 1000, and 8.3 per 1000, respectively.

Similar to the EPA and the CPSC, the FDA also used the NTP bioassay to estimate risks (Ex. 6-1). However a straight line extrapolation method was used instead of more complex low-dose extrapolation models. To make direct comparisons between mice exposed to 2000 ppm MC by inhalation in the NTP study and potential human exposure at different exposure levels and time intervals, time weighted average air concentrations were calculated. These averages represent the concentration of MC that individuals are exposed to on a continuous daily basis. For a consumer with an assumed exposure of 50 ppm MC in air for 5 minutes per day, 7 days a week, FDA calculated a time weighted average exposure of 0.174 ppm. Using similar calculations the average exposure for hair care specialists was 1.74 ppm. For a mouse in the NTP study exposed to 2000 ppm for 6 hours a day, five days a week the time weighted average was 357 ppm.

FDA assumed a linear dose-response model from zero dose to the experimental level of 2000 ppm (357 ppm time weighted exposure). Extrapolating from the incidence of benign and malignant neoplasms in female mice exposed at 357 ppm to average human exposures of 0.174 ppm (for consumers) and 1.74 ppm (for hair care specialists),

FDA estimated a lifetime cancer risk for consumers of 1 per 1000 to 0.1 per 1000 (depending on whether the animal-to-human dose comparison is based on mg/kg/day or ppm, respectively) and a lifetime cancer for hair care specialists of 10 per 1000 to 1 per 1000.

OSHA calculated risks employing the FDA approach for an industrial worker exposed 8 hours a day 5 days a week at OSHA's current PEL of 500 ppm. In this case the time weighted average for continuous exposure is 119 ppm. Using this value and extrapolating from the linear dose-response model results in a lifetime cancer risk ranging from 666 per 1000 to 66.6 per 1000 (based on mg/kg/day and ppm, respectively).

#### H. Pharmacokinetics

In the quantitative risk assessments previously described, the NTP bioassay was the primary study used to estimate the cancer risk for humans exposed to MC. The NTP bioassay provided data on statistically significant dose-response relationships which were deemed suitable for estimating human risks at expected human doses. In most cases an applied dose multistage procedure was used. However, OSHA has received several comments and studies which indicate that use of the applied dose risk assessment approach may be inappropriate because it does not account for the metabolic and pharmacokinetic differences between mice and humans (Exs. 8-14d, 8-16c, 8-16d, 8-16e, 8-30, 8-31, 8-32, 8-33, 10-6-A, 14a, 14b, 14c, 10-39). In particular, it has been hypothesized that the carcinogenicity of MC results from a metabolite produced by only one of the pathways that metabolizes MC, the glutathione-S-transferase (GST) pathway. Under this theory, the GST pathway, rather than the mixed function oxidase (MFO) pathway, is the carcinogenic pathway. Proponents of this theory also believe that the GST pathway is active only at high doses (greater than the saturation of the MFO pathway, approximately 500 ppm), and that the GST pathway is more active in mice than in humans. These comments and studies indicate that metabolism by the GST pathway, unlike metabolism by the MFO pathway, correlates well with observed lung and liver tumors in mice and that the carcinogenic response observed in mice does not occur in humans exposed at low doses. DOW Chemical Company and the European Council of Chemical Manufacturers' Federations (CEFIC) have been especially active in studying the metabolism of MC (Exs. 7-225, 8-14d, 8-32, 8-33, 14a, 14b, 14c).



The carcinogenic mechanism of action of MC has not been elucidated with anything approaching certainty. However, the evidence suggests that the GST pathway may have been the primary pathway which produced the observed carcinogenic response. OSHA also notes that, while the carcinogenic response in mice correlated with the dose of the parent compound (Ex. 7-8), the lack of reactivity of the parent compound and the lack of interspecies correlation of blood levels of MC and carcinogenic response (i.e., rat blood levels of MC are higher than mouse levels for equivalent doses, but mice are more susceptible to carcinogenic effects than rats), suggest that the parent compound did not have a primary role in carcinogenesis.

Some researchers have suggested that the potentially reactive metabolites of MC (produced by either metabolic pathway) are not long-lived enough to interact with DNA (Ex. 10-18). They suggest that MC may act by a non-genotoxic mechanism, such as cytotoxicity, to produce cancer in the mouse (Ex. 8-31). This hypothesis raises questions about the possibility of a threshold response (indicating that there is an exposure level below which MC would not act as a carcinogen) and regarding applicability of the NTP mouse data when assessing human cancer risk. OSHA feels that, although there is no conclusive proof regarding how MC causes cancer, there is suggestive evidence supporting the genotoxicity of MC.

OSHA does not discount the possibility that the parent compound or the products of the MFO metabolic pathway contribute to the carcinogenicity of MC. Also, it is possible that some MC metabolites may exert a genotoxic effect while the parent compound or other metabolites may act by other, non-genotoxic mechanisms which promote carcinogenicity. These possibilities raise questions as to the sensitivity of the pharmacokinetic models to the carcinogenic contributions of these factors.

Dow Chemical submitted documentation of a physiologically-based pharmacokinetic model (Exs. 8-14d and 10-6a), developed for MC by Reitz and Anderson, which described the rates of metabolism of the MFO and GST pathways and the levels of MC and its metabolites in various tissues of rats, mice, hamsters and humans. The model was presented as a basis for converting an applied (external) dose of MC to an internal dose of active metabolite in the lung and liver in various species under various MC exposure scenarios.

A series of differential equations was used to model the mass balance of MC and its metabolites in various physiologically defined compartments, including the lung, liver, richly perfused tissue, slowly perfused tissue, and fat. Metabolism via the MFO pathway was described by saturable Michaelis-Menton kinetics whereas GST metabolism was assumed to be first-order nonsaturable. The rate constants for the system of equations were estimated on the basis of measurement of partition coefficients, allometric approximations of physiological constants (e.g., lung weight), and estimated biochemical constants (e.g., Michaelis-Menton constants).

From the model's predictions, Reitz and Anderson concluded that the metabolites formed by the GST pathway were responsible for the lung and liver tumors observed in the NTP mouse bioassays. They based their conclusion on the observation that the model's predictions of the concentrations of MFO metabolites did not correlate with the mouse lung and liver tumor incidences observed in the NTP study, whereas the predicted GST metabolite concentrations in the lung and liver did correlate with the observed incidence of liver and lung tumors. That is, in bioassays, mice developed tumors at sites known to metabolize MC by the GST pathway at relatively high levels, whereas rats, which showed no evidence of lung or liver tumors, had low levels of GST activity in the lung and liver. However, this model cannot explain the increased incidence in mammary tumors observed in rats in the NTP study. Reitz and Anderson also suggested that the parent compound, MC, was not the carcinogenic agent because it is not sufficiently reactive and has not been shown to enhance mutagenicity in bacteria in the absence of GST enzymes. Thus, they concluded that the GST metabolites were most likely responsible for the observed carcinogenicity.

Reitz et al. (Ex. 7-225) have supported their model with measurements of the biochemical constants ( $K_m$  and  $V_{max}$ ) *in vitro* for the GST and the MFO metabolic pathways using MC as a substrate. Enzyme activities were determined by measuring the conversion of  $^{35}\text{Cl}$ -labeled MC to water-soluble products. Biochemical constants were then compared across species (mouse, rat, hamster and human). In the liver, the MFO activity was highest in the hamster, followed by the mouse, human and rat. Human values were much more variable than those of the rodent species. Human  $V_{max}$  for the liver MFO

pathway ranged approximately an order of magnitude and human  $K_m$  varied approximately three-fold. GST activity in liver was determined for mouse and human tissues only. Mouse liver had approximately 18-fold greater activity than human liver, but the human tissue had about a three-fold greater affinity ( $K_m$ ) for MC than the mouse.

In the lung, the activity of the MFO and GST enzymes was determined for a single substrate concentration. For the MFO pathway, mouse tissue had the highest activity, followed by hamster and rat. No MFO activity specific for MC was detected in the human lung tissue, although other MFO isozymes were demonstrated to be active in the tissue. For the GST pathway in lung, mouse tissue was the most active, followed by rat and human. No GST activity was detected in the hamster lung.

Reitz and Anderson stated that the model's predictions of the concentration of the GST metabolite in humans exposed to low doses of MC resulted in risks which were 140-170 fold lower than would be expected using EPA's applied dose risk assessment methods. Thus, Reitz and Anderson concluded that risk assessments which do not utilize pharmacokinetics may be subject to substantial error and may overestimate the risk in humans exposed to low concentrations of MC.

Metabolic studies submitted by CEFIC supported the conclusions of Reitz and Anderson. In one study (Ex. 8-32), the metabolism of MC was compared *in vitro* using rat, mouse and hamster lung and liver tissue as well as tissue from four human livers. The activity of the MFO pathway was determined by measuring the conversion of MC to carbon monoxide and the GST pathway activity was determined by measuring formaldehyde formation. In this study the most active tissue for metabolizing MC by the MFO pathway was the hamster liver, with similar rates observed in the mouse liver and lower rates observed in rat and human liver. In lung tissue, lower rates of MFO activity were observed for rat lung compared to rates in the mouse and hamster. Human lung tissue was not available so no results were presented for human lung. For the GST pathway, rates in the mouse liver were higher than in any other tissues. Low rates were observed in the mouse lung tissue but no activity was detected in either the hamster or human liver or the rat or hamster lung. GST activity in these tissues was further examined using  $^{35}\text{Cl}$ -labeled MC (Ex. 14b). In this *in vitro* study, GST activity was found in all tissue samples. Mice



continued to show higher levels of activity but the human tissue also showed some low activity, whereas previously this activity had not been detected.

In a second metabolic study (Ex. 8-33) by CEFIC, the metabolism of MC was assessed *in vivo* using F344 rats and B6C3F<sub>1</sub> mice, exposed by inhalation to 500, 1000, 2000 and 4000 ppm MC for 6 hours. From this study it was observed that the MFO pathway saturated at concentrations of 500 ppm or higher in both species, as measured by COHb levels. In rats, after saturation of the MFO pathway, there was a linear increase in the parent compound, MC, in the blood with corresponding increases in dose, indicating that little further metabolism of MC occurred by other pathways. However in mice, there was a non-linear relationship between dose increases and the level of MC in the blood after saturation of the MFO pathway, indicating that further metabolism might be occurring by another pathway. At high dose levels, the mouse also showed a 10-fold higher elimination rate of CO<sub>2</sub> than the rat. This finding was interpreted as further evidence that the GST pathway was more active in the mouse.

EPA has criticized (Ex. 7-128) the CEFIC metabolic studies (Exs. 8-32 and 8-33). Some of their criticisms addressed the methodologies used to detect MFO and GST activity in animals and in humans. In particular, the use of formaldehyde as a measure of GST activity was considered to be an insensitive measure of GST activity at low dose levels. The use of CO<sub>2</sub> as a marker for GST activity was also considered inappropriate, due to the fact that the MFO pathway may also generate CO<sub>2</sub>. Furthermore, EPA noted that few samples of human liver tissue and no samples of lung tissue were available to estimate GST activity. In the case of human liver tissue, it was questioned if four samples from accident victims provided an adequate basis upon which to assess human enzyme activity in general. Generally, when human tissue is used for *in vitro* enzyme measurements, small numbers of samples are available, and the medical history of the donors and the state of the tissue at the time of death are unknown. These factors make it difficult to extrapolate data collected from human tissue *in vitro* to the general population *in vivo*. In the case of the lung, CEFIC has implied (Ex. 10-39) that enzyme activity would be very low in human tissue because the measured human liver tissue activity was low compared to mouse liver. Due to the fact that

tissues may vary in enzymatic activity, it was questioned whether or not low liver activity would necessarily imply low lung activity.

In addition to metabolic studies of MC, CEFIC submitted studies concerning the cellular toxicity and genotoxicity of MC. In a 10-day inhalation toxicity study (Ex. 8-16c) CEFIC investigated the toxic effects of MC on mouse and rat lung and liver cells. After exposure to 2000 or 4000 ppm MC, the only toxic effect observed histologically was toxicity to the Clara cells of the mouse lung. Clara cells are believed by the authors to have a high potential for GST activity. It was concluded that the specific toxicity for Clara cells in the mouse, with no observed effect in the rat, suggested that there was a species difference in metabolic capacity. This interspecies difference in metabolic capacity, in turn, might account for the differences observed between species in tumor development. Clara cell toxicity was further examined in mice exposed to 4000 ppm MC 6 hours/day for 10 days (Ex. 14c). In the Clara cells, MFO enzymes were reduced by almost half; however, the GST enzymes were unaffected. This study supported an hypothesis generated by CEFIC (Ex. 8-16c) suggesting higher GST activity in these specialized cells, compared to GST activity in the whole lung. This higher activity in Clara cells may help to explain the lung tumor response observed in mice, which was higher than would be predicted on the basis of overall GST metabolism in the lung.

Other studies submitted by CEFIC suggested that MC induces carcinogenicity by a non-genotoxic mechanism, which most likely operates primarily at high doses. In a mouse micronucleus test (Ex. 8-30), mice exposed to single intragastric doses of MC did not show a significant increase in micronuclei in their erythrocytes. Micronuclei are formed as a result of chromosomal damage induced by test compounds and are easily measured in erythrocytes. In this test, since no significant increases in micronuclei were detected, the authors concluded that MC was not genotoxic to the mouse.

This study has been criticized because the micronucleus tests for genotoxicity require the reactive metabolites of MC to be produced in bone marrow or to be stable enough to reach the bone marrow. There is no evidence at this time that MC metabolites produced in the liver or other organ sites are stable enough to reach the bone marrow or that the bone marrow has any metabolic capability for

MC. Also, bone marrow has not been described as a target for MC toxicity.

In another study to test for genotoxicity, CEFIC examined the *in vivo* interaction of MC and its metabolites with rat and mouse lung and liver DNA after inhalation exposure to 4000 ppm <sup>14</sup>C-MC (Ex. 8-16d). In this experiment, no MC-induced DNA adducts were detected after MC exposure and it was concluded by the authors that MC or its metabolites did not react with the DNA and, therefore, MC was not genotoxic.

The detection limits of these experiments to determine whether MC caused DNA adducts (DNA alkylation) were questioned by the EPA. When the negative DNA adduct data was presented, the investigators' data did not show the detection of 5-methylcytosine (a normal minor base in DNA which comprises approximately 3% of the cytosines). This base is not a DNA adduct, but is labeled by <sup>14</sup>C-formate in the protocol used in this experiment and should have been easily detected. The concentration of DNA adducts from exposure to a potent DNA-adduct forming chemical would be expected to be much lower than 3% (the concentration of 5-methylcytosine in untreated DNA). Since apparently no 5-methylcytosine was detected by the methods described in this experiment, there is doubt as to the sensitivity of the assay for detecting DNA adducts produced by a genotoxic compound, particularly a weakly genotoxic compound. In a related issue, *no in vivo* positive control for DNA-adduct formation was included in the protocol. This positive control is important to determine the levels at which DNA adducts can be detected, and to ensure that the assay is working properly. A further criticism of this experimental protocol was that the dose used (4000 ppm) was too low to detect short-term DNA adduct formation. (4000 ppm was the highest dose used by the NTP chronic bioassay and was designed to elicit minimal toxicity over a 2-year exposure period. This dose would be too low for the purpose of detecting short-term genotoxic effects.)

To further test for genotoxicity, CEFIC conducted an *in vivo* and *in vitro* study to determine if MC induced unscheduled DNA synthesis (UDS) (Ex. 8-16e). UDS is an indication of DNA replication and repair in response to chromosomal damage. In the *in vivo* study, mice and rats were exposed by inhalation to 2000 or 4000 ppm, for 2 or 6 hours. In the *in vitro* study, isolated hepatocytes of rats and mice were exposed to 500, 1000, 2000 and 4000 ppm of gaseous MC for 8



hours. No UDS was detected in either species, in either study, indicating that no detectable DNA damage occurred using these protocols.

Studies of UDS *in vivo* are of questionable value because these protocols are primarily used when extrahepatic metabolism of MC is suspected. The MC metabolites (produced in a site outside the liver) then must be stable enough to reach the liver and interact with liver DNA in order to be measured as *in vivo* UDS in this assay. There is currently no evidence that metabolites of MC are produced in large enough quantities at extrahepatic sites or that the metabolites are stable enough to be transported from the site of metabolism to the liver to attack DNA. Negative responses in the two assays described above do little to confirm or refute the hypothesized genotoxic mechanism of action for MC and limit the usefulness of this data in the interpretation of the genotoxicity of MC.

As with the DNA alkylation study discussed above, the doses used here in the *in vitro* and *in vivo* genotoxicity studies were too low for researchers to be confident of detecting measurable effects. In order to accurately characterize the genotoxic potential of MC, these studies would need to be repeated at higher doses.

In order to determine if a non-genotoxic mechanism, such as increased cell turnover, was responsible for the carcinogenicity observed in mouse bioassays, CEFIC exposed mice by inhalation to 4000 ppm MC and then examined the mice for increased scheduled DNA synthesis (Ex. 8-31). Scheduled DNA synthesis represents cell replication, and not DNA repair. Chemicals which are cytotoxic at high doses may induce increased cell division and thus enhance the background levels of tumors. In the case of mouse hepatocarcinogenicity, such a cell division increase can be measured by an increased incidence of S-phase hepatocytes. In this study a statistically significant but small increase in S-phase hepatocytes was observed. It was concluded that this response suggested only a tentative correlation between increased cell proliferation and hepatocarcinogenicity in the mouse.

In this study, as in those cited above, the dose used was the same as the highest dose from the NTP chronic bioassay. In order to determine if MC increases cell turnover and acts as a non-genotoxic carcinogen, it would be necessary to repeat the short-term experiments with higher doses of MC, or to examine the effects of chronic administration of lower doses of MC on cell replication.

OSHA has determined that the information from the CEFIC studies is insufficient to conclude that MC is non-genotoxic. For example, the negative responses from the mouse micronucleus (Ex. 8-30), UDS (Ex. 8-16e) and DNA interaction tests (Ex. 8-16d), which were interpreted as evidence that MC is non-genotoxic, might also be interpreted as evidence that MC is a weak mutagen (e.g., a weak mutagen might evoke a response below the level of detection of the assay). Also, the S-phase hepatocyte study (Ex. 8-31), conducted to determine the possibility of cytotoxicity rather than genotoxicity as a cause of carcinogenic response, showed a small positive response, but the response was interpreted by the authors as unclear evidence of cytotoxicity. Therefore, OSHA continues to seek evidence regarding the extent to which MC acts by a genotoxic mechanism during carcinogenesis.

In general, although pharmacokinetic models, when properly defined, can be used to estimate the internal doses for various chemicals in various organs, they do not provide information on (1) which chemical or metabolite is the carcinogen, (2) the differences in sensitivities of target tissues to concentrations of chemicals or (3) whether the site of carcinogenic response is the same from one species to the next.

In addition, methods have not been developed for quantifying the uncertainty of the internal dose estimates. Potentially quantifiable uncertainty in any pharmacokinetic model arises from two major sources of statistical variability: Inherent biological variability between members of the same species; and experimental error in estimating average values for model parameters (due to technological limitations and to sampling error in those quantities which have appreciable biological variability.) Physiological parameters (such as ventilation rates and organ and body weights) may be expected to evidence considerable variability, which may cause large variations in internal doses within members of a single species. Biochemical parameters (such as metabolic parameters and partition coefficients representing the relative affinities of the chemical for air, blood, and various organ tissues) may be subject to less inherent variability, but these must be estimated (sometimes indirectly) from experimental data.

In the specific case of MC, the model developed by Reitz and Anderson, appears to provide a plausible description of the absorption, distribution and elimination of MC.

However, the model's description applies only to the lung and liver. In rats, an excess of mammary tumors was observed that was not explained by the Reitz and Andersen model. In humans, other sites may metabolize MC and be vulnerable to the toxic or carcinogenic effects of MC.

In the preliminary draft of its Update to the HAD for MC (Ex. 7-128), EPA has also made a number of criticisms specific to the pharmacokinetic model developed by Reitz and Anderson. This draft document has been approved by the Scientific Advisory Board (SAB) and the risk estimates based on this document have been accepted by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) for inclusion in the Integrated Risk Information System as the official interim stance of the EPA concerning MC. The citation in the IRIS data base contains a note explaining that the risk estimate comes from a draft document which has been approved by the SAB and the CRAVE. Criticisms contained in this document primarily come from critical analyses performed by the Hazard/Risk Assessment Committee of the Integrated Chlorinated Solvents Project. This committee, chaired by EPA and comprised of representatives from CPSC, FDA, and OSHA, has been reviewing and evaluating the models and metabolic studies in order to determine their use/effect in estimating risk to humans.

Overall the model structure was considered by EPA to be a plausible description of MC metabolism. The major uncertainties were felt to be chiefly from the input data for the model, some of which might contribute a source of error that might influence the calculation of internal doses of GST metabolites. For example, EPA observed that the model does not take into account the fact that MC may become sequestered in the lipid rich regions of various tissues. Over time the sequestering into the lipid areas could affect the disposition and metabolism of MC. Such an effect, unless taken into account, could alter the model's ability to correctly predict the GST metabolite concentrations. Also it was noted that the tissue/air partition coefficients input for the model were measured using homogenized tissue rather than intact tissue. In homogenizing tissues, the structure of the tissue is destroyed and thus the tissues may not adequately portray the processes occurring *in vivo* that determine partitioning. With regard to breathing rate input data, EPA observed that the authors of the model used a higher breathing rate for mice



and a lower breathing rate for humans than those standardly employed by EPA. In particular Reitz and Andersen's model used breathing rates for humans at rest. This value may not accurately reflect the rate at which humans may breathe MC in the occupational setting. EPA, in its analysis of the pharmacokinetic data, used an average daily breathing rate of 20 m<sup>3</sup>/24 hour day (as compared with OSHA's estimated breathing rate of 9.8 m<sup>3</sup>/8 hour workshift of exposure). Choice of breathing rate would, in turn, alter the model's prediction of GST metabolites in humans after MC exposures (i.e., humans exposed to MC during physical exertion would take in more MC than a sedentary individual exposed to the same MC concentration).

EPA also pointed out that the metabolic rates for each pathway were calculated by mathematical optimization rather than by experimentation. By this process values were selected which optimized the model's ability to predict the loss of MC from a closed inhalation chamber as the compound was inhaled and metabolized by animals. EPA noted that many alternative metabolic rates could be used to optimize the experimental data. Some of these alternate rates could change the model's prediction of internal dose. Furthermore, in order to calculate the relative amount of activity of each pathway in the liver and the lung, surrogate substrates were used in place of MC. EPA feels that this may be an inappropriate method because the enzyme activity not only varies from species to species but also from tissue to tissue, such that each tissue may have its own array of enzymes. These surrogates may not be an appropriate measure of these pathways' activities for MC.

Despite the above-noted uncertainties, EPA has concluded that the Reitz and Anderson model is a reasonable method for describing and predicting the disposition of MC and its metabolites in human tissues. As the model is further refined, these uncertainties may be reduced. However, even with refinement of the pharmacokinetic model a major question remains: What is the appropriate way to use internal doses calculated from the model to estimate the risk to humans?

In the draft Update of its HAD (Ex. 7-129), EPA proposed a method to incorporate the pharmacokinetic model to develop estimates of risk. In this approach the pharmacokinetic model was used to estimate the internal dose in mice at exposure levels tested in the NTP bioassay. Using these doses and

the tumor responses in the NTP bioassay, a dose-response curve was constructed using the multistage procedure. Liver data were fitted by a two stage model and lung data were fitted by a one stage model. Next the pharmacokinetic model was used to calculate the internal dose of GST metabolite in human liver and lung.

These doses were then scaled by the surface area correction factor and from these corrected doses the risks were calculated according to the dose-response curve. EPA felt that the surface area correction factor should continue to be applied to internal doses in the same manner as it has been used with applied doses. This is based on EPA's belief that, as reflected in its previous risk assessments, the surface area correction factor was applied to correct for metabolic differences between species and to correct for the differences in a chemical's potency between species. Differences in potency reflect many factors in addition to metabolism (e.g., differences in responsiveness to a given internal dose, number of cells exposed, immunosurveillance, DNA repair capability, species longevity, and basal cell division rate). EPA has indicated that, because one cannot determine the magnitude of the effect that any one factor may have on species sensitivity, that Agency would continue to apply a surface area correction factor on dose.

Using the procedure outlined above, EPA calculated a revised lifetime risk estimate of 0.47 per million for a continuous exposure to 1 ug/m<sup>3</sup>. This constitutes an approximate nine-fold reduction from its previous lifetime risk estimate of 4.1 per million in which applied doses were used.

EPA calculated its risk estimates based on continuous lifetime exposure to extremely low ambient concentrations of MC (1 ug/m<sup>3</sup> = 0.000288 ppm) compared to OSHA's risks calculated at occupational exposures of 25 ppm (= 86,750 ug/m<sup>3</sup>). The risk assessment developed by OSHA, which was based on applied dose methods, was extrapolated from the calculated occupational risks at 25 ppm to lifetime continuous exposure at 1 ug/m<sup>3</sup>, so that the OSHA numbers were comparable to those produced in the EPA assessment. OSHA's assessment predicted a risk of 0.18 per million after lifetime continuous exposure to 1 ug/m<sup>3</sup>. This value is close to that calculated by EPA after incorporation of the pharmacokinetic data and is 23-fold lower than the EPA applied dose estimate.

Based on these estimates, EPA noted that "In view of the uncertainties

involved, the changes in DCM's carcinogenic potency that results from different uses of the available pharmacokinetic information are not, in practical terms, very distinct" (Ex. 7-128). OSHA notes that EPA has a mandate to protect the general public from low level environmental hazards, which enables that Agency to regulate hazards when the population risk is 1 per million to 1 per ten thousand. In this case, EPA's incorporation of pharmacokinetics was not a critical factor in that Agency's decision regarding the regulation of MC. On the other hand, as discussed above, OSHA's mandate to regulate MC hinges on the determination that the population risk for occupational exposure at a particular exposure level is approximately 1 per thousand or greater. Accordingly, considering the risk numbers which OSHA generated using the applied dose multistage procedure, any change in the risk estimates prompted, for example, by the incorporation of pharmacokinetic data, will directly impact OSHA's decision regarding permissible exposure limits for MC. For this reason, OSHA believes it is necessary to carefully evaluate the pharmacokinetic and mechanistic data and assess the impacts of the uncertainties in the pharmacokinetic data before incorporating that data into its risk assessment for MC.

The CPSC has incorporated pharmacokinetics to update its previous risk estimates by a different method than used by the EPA (Ex. 7-126). The CPSC felt that it was premature to extrapolate from species to species based on pharmacokinetic information and therefore the pharmacokinetic information was used to extrapolate only from high to low doses within each species. As a first step the animal doses tested in the NTP bioassay were corrected by a surface area correction factor. These doses were modified by dividing the doses by a high-to-low dose extrapolation factor derived from output from the pharmacokinetic model. This factor is used to describe the nonlinear aspect of the dose-response curve associated with the metabolism of MC. These modified doses and the tumor responses from the NTP bioassay were put into the multistage model to construct the dose-response curve. The human doses were corrected by the same high-to-low dose correction factor and were then used to calculate risks according to the dose-response curve. CPSC calculated a maximum likelihood estimate (MLE) lifetime risk of 2.3 per thousand for continuous exposure to 1 mg/kg/day based on carcinomas alone



and a lifetime risk of 5.2 per thousand per mg/kg/day based on carcinomas and adenomas. (As in its previous risk assessment, estimates for male and female mice were averaged for the lung and liver separately and then the lung and liver estimates were added together). This represents approximately a factor of two reduction from CPSC's applied dose risk estimates.

In a preliminary investigation, K.S. Crump and Company have also compared the difference between applied and internal dose risk estimates (Ex. 7-127). Using Reitz and Anderson's pharmacokinetic model, Crump and Company calculated human risk estimates for the same data sets analyzed previously in their quantitative risk assessment using external doses. Data sets were analyzed using a one-hit model, with parameters estimated from the experimental tumor data, and the internal doses derived from the pharmacokinetic model. Internal doses were expressed as either the concentration of MC in target tissue, the concentration of MC in arterial blood or the concentration of GST metabolite in target tissue. For a given data set the risk estimates were similar for each measure of internal and external adjusted dose. For example, at an exposure of 500 ppm, the 95% upper limit of human risk based on female mouse lung adenomas or carcinomas and the GST metabolite was 9.12 per thousand. This represents an approximate six-fold reduction from the 95% upper limit on human risk estimated previously without pharmacokinetic data (57.7 per thousand). For the same data set, an estimate of extra risk corresponding to an occupational exposure of 1 ppm was 10.8 per million compared to an extra risk of 119 per million without pharmacokinetic data, an approximate eleven-fold reduction. The differences in reduction of risk at high and low doses of MC reflect the nonlinearity of the pharmacokinetic model for MC.

Two additional risk assessments incorporating pharmacokinetics have been submitted by Reitz et al. (Ex. 7-225) and ECETOC (Ex. 10-39). Reitz et al. used the Reitz and Anderson pharmacokinetic model and internal doses were calculated from the model in a manner similar to that described by EPA, except that no surface area corrections were made to internal doses. Species were assumed to be equally sensitive to equal internal doses of GST metabolites. The internal doses were calculated for female mice at exposure levels tested in the NTP bioassay and these doses were used in four different dose-response models: the linearized

multistage, the Probit, the Weibull and the Logit. The authors reported that each model fit the data equally well. However, the predicted upper bound risk estimates differed by 5 to 15 orders of magnitude. Based on female mouse lung adenomas and carcinomas the multistage model estimated a lifetime unit risk of 0.037 per million for continuous exposure to 1  $\mu\text{g}/\text{m}^3$  which is two orders of magnitude lower than the unit risk of 4.1 per million calculated by EPA without pharmacokinetics and one order of magnitude lower than the unit risk of 0.47 per million calculated by EPA using pharmacokinetics. For an occupational dose of 50 ppm the multistage model predicted an upper bound risk of lung tumor of 14 per million. This value is approximately two orders of magnitude lower than the upper bound risk estimate of 592 per million calculated by Crump without the use of pharmacokinetics.

ECETOC, using data obtained through the CEFIC/ECETOC research program, modified the pharmacokinetic model developed by Reitz and Anderson and used the internal doses calculated from this modified model to conduct their risk assessment. Internal doses were calculated for the GST metabolite for female mice at exposure levels tested in the NTP bioassay. These doses and the corresponding observed tumor incidences were used in three different dose-response extrapolation models: the multistage, "one-hit" and Weibull. The modified pharmacokinetic model was also used to calculate human internal doses of GST metabolites. These doses were adjusted to a lifetime average daily dose and run in the risk models. The authors stated that the one-hit model provided a poor fit to the data and thus did not report those results. For both the quadratic multistage and Weibull models, the risks were calculated for both the lung and the liver and also for both organs combined. From the multistage model, at 10 ppm, the MLE of risk for lung tumor was 0.00612 per million. This value was approximately five orders of magnitude lower than the MLE risk estimate of 934 per million calculated by Crump without the use of pharmacokinetics and four orders of magnitude lower than the MLE risk of 109 per million calculated by Crump using pharmacokinetics. At 500 ppm the MLE risk estimate for lung tumors from the multistage model was 17.5 per million. This value was three orders of magnitude lower than the MLE risks calculated by Crump at 500 ppm without pharmacokinetics (45.5 per thousand), and two orders of magnitude

lower than the risk estimates using pharmacokinetics, 7.3 per thousand.

The above risk assessments indicate that the incorporation of information from the pharmacokinetic model for MC can reduce previous risk estimates derived using applied dose methods. In some cases the risk estimates were reduced by a factor of two while in other cases there was up to five orders of magnitude difference. The larger differences generally occurred in those cases in which internal doses predicted from the pharmacokinetic model were used in quantitative risk models without any corrections for differences in species sensitivity (e.g. a surface area correction factor).

At this time, OSHA feels that use of pharmacokinetic parameters to adjust internal dose of MC may be premature. The primary reason for this is that a major assumption must be made that the GST pathway is the only carcinogenic pathway, and that there is no contribution to the carcinogenic process by metabolites from other pathways or by the parent compound itself. If it is determined that MC or MC metabolites from the MFO pathway contribute to the carcinogenicity of MC, the pharmacokinetic model would not provide an accurate estimate of risk.

Another disadvantage of the model is that it does not account for the possibility of MC metabolism or carcinogenesis at sites other than the lung or liver. In order to account for species differences in potency, CPSC has limited its use of pharmacokinetics to high-to-low dose extrapolation within species whereas EPA corrected internal doses by a surface area correction factor to extrapolate both from high to low doses and from species to species. These reduced risk estimates are a result of incorporating pharmacokinetic information specific to the lung and liver. The model does not provide information for other potentially active sites in the body (for example, it does not address the excess tumors identified in the mammary glands of rats exposed to MC). Because metabolic activity may vary from tissue to tissue within a species and also because one cannot be sure whether the site of carcinogenic response is the same from one species to the next, it may not be appropriate to base reductions in risk estimates solely on pharmacokinetic information from two tissues.

The pharmacokinetic model also has little ability to differentiate differences in tissue sensitivity between species to a given dose of MC. The EPA and the CPSC have used correction factors based on body weight or surface area in



part to account for these differences. OSHA agrees with the application of these correction factors in cases where pharmacokinetic data is used. If analysis of the evidence collected in the record indicates that pharmacokinetic data should be used to adjust the internal MC dose for use in occupational risk estimates, OSHA feels these correction factors should continue to be applied.

Other uncertainties surrounding pharmacokinetic models and their use for risk assessment are the validity of using data extrapolated from human and animal tissue *in vitro* to predict human risk during occupational exposures, and the validity of estimated pharmacokinetic parameters, such as partition coefficients in the model.

At this time, OSHA feels it is most prudent to continue to use the applied dose methods in its assessment of risk. Serious consideration is being given to pharmacokinetics and OSHA invites comment (see Issue 6 for specific questions) on the appropriateness of the pharmacokinetic data for assessment of occupational exposures, on the choice of risk model and how the risk model is affected by pharmacokinetic data, and on the sensitivity of the pharmacokinetic model parameters to errors or refinements in their estimation. OSHA will evaluate the utility of pharmacokinetic models to predict human risk from occupational exposure to MC and consider the uncertainties associated with these models during the rulemaking process.

### I. Conclusions

Based on its evaluation of the studies and its review of quantitative risk assessments performed outside the Agency, OSHA believes that there is an excess risk of cancer death from exposure to MC. OSHA endorses K.S. Crump and Company's approach to the MC quantitative risk assessment, and concludes that risk estimates based on the NTP mouse lung tumor data will be used in making the preliminary determination of risk.

OSHA believes that the multistage model, at this time, is the most appropriate model for the prediction of excess risk from exposure to MC. The curve shows good fit to the observed data and was employed in almost all quantitative risk assessments submitted to the record.

OSHA also believes that, despite the fact that the some of the epidemiological data has been interpreted as non-positive, the human studies can be used to calculate upper confidence limits on human risk. These upper limits demonstrate the reasonableness of the

animal data, insofar as the risk estimates derived from the animal data are within the range of the estimates based on the epidemiological data.

Although the metabolism of MC has been extensively studied and plausible models of the mechanism of action of MC have been generated, there is still substantial uncertainty as to the carcinogenic mechanism of action of MC. The uncertainty surrounding the possible contributions of the parent compound or metabolites from the MFO pathway to the carcinogenic process remains the single most critical factor for validating the usefulness of the pharmacokinetic modeling approach. Other areas of uncertainty include the organ specificity of the model (excluding the possibility of metabolism or carcinogenesis at sites other than the lung or liver) and the extrapolation of human enzyme activity from *in vitro* data.

The quantitative risk assessment produced using the NTP bioassay is intended to assess some measure of the carcinogenic potency of MC. It is not designed for or limited to the identification of a specific target site in humans. The pharmacokinetic and metabolic studies to date have concentrated on specific sites such as the liver and lung tissue and have not examined other tissues. From this approach it is not clear that the risk of cancer at sites other than the liver and the lung can be excluded. Due to the limitations of the model described above and the associated uncertainties, OSHA does not feel that it is appropriate at this time to incorporate the pharmacokinetic model, as submitted, into its preliminary quantitative risk assessment for MC.

Thus, at this time, OSHA concludes that the lifetime estimate of risk from exposure to MC at the current 8-hour TWA of 500 ppm is 33 to 45 excess deaths per thousand (95% confidence limits of 50 to 58 excess deaths per thousand). Such risks warrant OSHA regulatory action to reduce occupational exposure to MC.

In determining the level to which the permissible exposure limit should be lowered, several alternative 8-hour TWAs (100, 50, 25, 10, and 1) were considered by the Agency, as shown in Table 10. OSHA believes that compliance with the proposed 25 ppm TWA is technologically and economically feasible based on the Agency's knowledge of available control technology and on the Agency's awareness that several industries or industry segments are presently controlling exposures to or very near this level. OSHA's preliminary analysis of technological and economic

feasibility of the proposal is discussed in the following section of the preamble.

TABLE 10.—ESTIMATES OF EXCESS CANCER DEATHS PER 1000 WORKERS EXPOSED TO METHYLENE CHLORIDE \*

Exposure (ppm)	Excess cancer deaths	Cancer death reduction
500	33.2-45.5	
100	6.68-9.26	79%
50	3.34-4.64	90%
25	1.67-2.32	95%
10	0.67-0.93	98%
1	0.067-0.093	99%

\* Occupational Exposures of 45 years without consideration of Pharmacokinetic data in risk estimates.

### IX. Significance of Risk

In the 1980 benzene decision, the Supreme Court, in its discussion of the level of risk that Congress authorized OSHA to regulate, indicated when a reasonable person might consider the risk significant and take steps to decrease or eliminate it. The Court stated:

It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*I.U.D. v. A.P.I.*, 448 U.S. 607, 655).

The Court further stated that "while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is significant will be based largely on policy considerations." The Court added that the significant risk determination required by the OSH Act is "not a mathematical straitjacket," and that "OSHA is not required to support its findings with anything approaching scientific certainty." The Court ruled that "a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and that] \* \* \* the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656).

OSHA's overall analytic approach to regulating occupational exposure to particular substances is a four-step



process consistent with recent court interpretations of the OSH Act, such as the benzene decision, and rational, objective policy formulation. In the first step, OSHA quantifies the pertinent health risks, to the extent possible, performing quantitative risk assessments. The Agency considers a number of factors to determine whether the substance to be regulated poses a significant risk to workers. These factors include the type of risk presented, the quality of the underlying data, the reasonableness of the risk assessment, the statistical significance of the findings and the significance of risk [48 FR 1804, January 14, 1983]. In the second step, OSHA considers which, if any, of the regulatory provisions being considered will substantially reduce the identified risks. In the third step, OSHA looks at the best available data to set permissible exposure limits that, to the extent possible, both protect employees from significant risks and are technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to fulfill its statutory mandate.

The current OSHA standard for MC was designed to prevent irritation and injury to the neurological system of the employees exposed to MC. In 1985, the National Toxicology Program (NTP) released the results of their MC rodent lifetime bioassays. Those results indicated that MC is carcinogenic to rats and mice. As discussed in the Events Leading to the Proposed Standard section, based on the NTP findings, EPA now considers MC a probable human carcinogen, and NIOSH regards MC as a potential occupational carcinogen and recommends controlling the exposure to MC to the lowest feasible level. In 1988, ACGIH classified MC as an industrial substance suspected of carcinogenic potential for man. As discussed in the Health Effects section, OSHA has determined, based on the NTP data, that MC is a potential occupational carcinogen. Having determined, as discussed in the Preliminary Quantitative Risk Assessment section, that the NTP study provided suitable data for quantitative analysis, OSHA performed quantitative risk assessments to determine if MC presents a significant risk at the current PELs.

OSHA prefers to use the multistage model of carcinogenesis in quantitative risk assessment. The multistage model is a mechanistic model based on the biological assumption that cancer is induced by carcinogens through a series of stages. The model generally is considered conservative, in the sense that it risks error on the side of

overprotection rather than underprotection, because it assumes no threshold for carcinogenesis and because it is approximately linear at low doses. The Agency believes that this model conforms most closely to what we know of the etiology of cancer. OSHA believes that the use of such a model is prudent public health practice. OSHA's preference is consistent with the position of the Office of Science and Technology Policy which recommends that "when data and information are limited, and when much uncertainty exists regarding the mechanisms of carcinogenic action, models or procedures that incorporate low-dose linearity are preferred when compatible with limited information (Ex. 7-227).

Several comments and studies, submitted to OSHA have suggested that the current applied dose approach for risk assessment should be replaced by assessments using the delivered dose of MC (Exs. 8-14d, 8-18c, 8-16d, 8-16e, 8-30, 8-31, 8-32, 8-33, 10-6-A, 14a, 14b, 14c, 10-39). The delivered dose is described by pharmacokinetic models of MC fate and metabolism, which may account for metabolic and pharmacokinetic differences between rodents and humans. While OSHA is interested in receiving and evaluating risk assessments produced using pharmacokinetic models, serious questions remain concerning the application of these models in the risk assessments prepared by OSHA. Specifically, the Agency is concerned that the pharmacokinetic model (1) assumes that the only carcinogenic metabolite is produced by the GST pathway; (2) relies on *in vitro* data to supply many of the biochemical constants; (3) extrapolates from a very small database of human metabolic data (especially for the lung); and (4) assumes that the lung and liver are the only target sites for carcinogenesis across all species. The Agency notes that the NTP and the Chemical Industry Institute of Toxicology are continuing investigations of the mechanisms by which MC produces cancer in rodents. OSHA will carefully evaluate the results of those studies, as they become available.

Other concerns with the use of pharmacokinetic models include the lack of quantification of the reduction in uncertainty in the risk assessment process that should follow from using a model which predicts risk based on delivered dose rather than applied dose. Also, even when pharmacokinetic data have been used in risk assessments, there has been no consensus as to how the data should be incorporated, or how that incorporation affects use of the

multistage model of cancer risk. OSHA has determined that it is not appropriate at this time to incorporate pharmacokinetic models in the MC cancer risk assessment. OSHA is soliciting information through an issue included in this proposed rule to address various concerns about the pharmacokinetic models and the risk assessment process (see Issue 6 for specific questions).

As discussed in the Health Effects and Preliminary Quantitative Risk Assessment sections, OSHA has evaluated four MC rodent bioassays (Exs. 4-35, 4-25, 7-29, 7-30, 7-31) to select the most appropriate bioassay as the basis for a quantitative risk assessment. These bioassays have been conducted in three rodent species (rat, mouse, and hamster) using two routes of administration (oral and inhalation). The NTP study (rat and mouse, inhalation) was chosen for a quantitative risk assessment because it provides the clearest evidence of the carcinogenicity of MC from both a toxicological and statistical standpoint (Exs. 12, 7-127). In the NTP study, MC induced significant increases both in incidence and multiplicity of alveolar/bronchiolar and hepatocellular neoplasms in male and female mice.

Once the incidences of alveolar/bronchiolar and hepatocellular neoplasms in male and female mice were chosen as the most appropriate data sets, the multistage model of carcinogenesis was used to predict a lifetime excess risk of cancer from occupational exposure to MC at several concentration levels. OSHA's best estimate of excess cancer risks at the current PEL of 500 ppm (8-hour TWA) are 33 to 45 per 1,000 and at the proposed PEL of 25 ppm are 1.67 to 2.32 per 1,000 employees for 45 years of exposure.

As discussed in more detail in the Health Effects Section, above, human data concerning the carcinogenicity of MC was presented in three epidemiology studies. In a study of cellulose triacetate fiber production (MC used as solvent) workers, marginally increased incidence of liver/biliary cancer (Ex. 7-260) was noted. Although the case numbers were small and the exposure information limited, this epidemiological evidence is consistent with findings from animal studies and indicates that there may be an association between human cancer risk and MC exposure. A study of workers in photographic film production was non-positive (7-163). However, the exposures experienced by these workers may have been much less than in the cellulose



triacetate fiber plant. The study of workers in paint and varnish manufacture was also non-positive (Ex. 10-29b). Exposures in these plants were not documented and workers were exposed to multiple chemicals during their employment.

The proposed STEL of 125 ppm for 15 minutes is primarily designed to protect against non-cancer risks, although there is evidence that reducing the GST metabolite production by reducing short term exposure to high concentrations of MC may also lower the cancer risk. As discussed in the Health Effects section, there are substantial risks of CNS effects and cardiac toxicity resulting from acute exposure to MC and its metabolites. CNS effects have been demonstrated at concentrations as low as 175 ppm. A STEL of 125 ppm for 15 minutes would be protective against the CNS effects described. Metabolism of MC to CO increases the body burden of COHb in exposed workers. Levels of COHb above 3% COHb may exacerbate angina symptoms and reduce exercise tolerance in workers with silent or symptomatic heart disease. Smokers are at higher risk for these effects because of the already increased COHb associated with smoking (COHb ranges from 2 to 8% in most smokers). Limiting short term exposure to 125 ppm for 15 minutes will keep COHb levels due to MC exposure below the 3% level, protecting the subpopulation of workers with silent or symptomatic heart disease and also limiting the additional COHb burden in smokers.

Further guidance for the Agency in evaluating significant risk is provided by an examination of occupational risk rates, legislative intent, and decisions of the Supreme Court. For example, in the high risk occupations of mining and quarrying (Division B), the average risk of death from an occupational injury or an acute occupationally-related illness over a lifetime of employment (45 years) is 15.1 per 1,000 workers. Typical occupational risks of deaths for all manufacturing (Division D) are 1.98 per 1,000. Typical lifetime occupational risk of death in an occupation of relatively low risk, like retail trade, is 0.82 per 1,000 (Division G). (These rates are averages derived from 1984-1986 Bureau of Labor Statistics data for employers with 11 or more employees, adjusted to 45 years of employment, for 50 weeks per year).

There are relatively few data on risk rates for occupational cancer, as distinguished from occupational injury and acute illness. The estimated cancer fatality rate from the maximum permissible occupational exposure to

ionizing radiation is 17 to 29 per 1,000 (47 years at 5 rems; Committee on Biological Effects of Ionizing Radiation (BEIR) III predictions). However, most radiation standards require that exposure limits be reduced to the lowest level reasonably achievable below the exposure limit (the ALARA principle). Consequently, approximately 95% of radiation workers have exposures less than one-tenth the maximum permitted level. The risk at one-tenth the permitted level is 1.7 to 2.9 per 1,000 exposed employees.

Congress passed the Occupational Safety and Health Act of 1970 because of a determination that occupational safety and health risks were too high. Congress therefore gave OSHA authority to reduce above-average or average risks when feasible. Within this context, OSHA's preliminary best estimates of risk from occupational exposure to MC at the current 8-hour TWA PELs are substantially higher than other risks that OSHA has concluded are significant, are substantially higher than the risk of fatality in high-risk occupations, and are substantially higher than the example presented by the Supreme Court. Consequently, OSHA preliminarily concludes that its best estimate of risk, 33-45 cancer deaths per 1,000 workers, associated with the current 8-hour TWA PEL of 500 ppm presents a significant risk. OSHA's estimate of risk, derived from the same data and model, shows that, at the proposed exposure level of 25 ppm, the risk is 1.67-2.32 per thousand, which would also be significant based on the above reasoning.

Because of the feasibility limitations discussed in the Summary of Preliminary Regulatory Impact and Regulatory Flexibility section, OSHA integrated other protective provisions into the proposed standard to further reduce the risk of developing cancer among employees exposed to MC. Employees exposed to MC at the proposed 8-hour TWA PEL limit without the supplementary provisions would remain at risk of developing adverse health effects, so that inclusion of other protective provisions, such as medical surveillance and employee training, is both necessary and appropriate. For workers exposed over the action level, illness and injury may be identified at an early enough stage to prevent irreversible damage. Consequently, the programs triggered by the action level will further decrease the incidence of disease beyond the predicted reductions attributable merely to a lower PEL. As a result, OSHA preliminarily concludes that its proposed 8-hour TWA PEL of 25

ppm and associated action level (12.5 ppm) and STEL (125 ppm) will protect employees and that employers who comply with the provisions of the standard will be taking reasonable steps to protect their employees from the hazards of MC.

#### X. Summary of Preliminary Regulatory Impact and Regulatory Flexibility Analysis

The objective of this analysis is to measure the regulatory impact of changing the MC PEL to an 8 hour time-weighted average (TWA) of either 50 ppm or 25 ppm, together with associated action levels, short-term exposure limits (STELs) and ancillary requirements. The primary sources of information for this analysis are studies conducted for OSHA by CONSAD Research Corporation, Economic Analysis of OSHA's Proposed Standards for Methylene Chloride, 1990 (Ex. 15), and Economic Analysis of OSHA's Proposed Standards for Methylene Chloride in the Construction and Shipbuilding Industries, 1991, (Ex. 15C).

Based on production and process technology data collected from a literature search and during site visits to industrial facilities, OSHA believes it is technologically feasible to achieve the proposed PEL of 25 ppm through implementation of traditional and conventional engineering controls. However, OSHA's contractor chose a conservative model and projected that a portion of exposed workers, within certain industrial segments covered by the standard, would incur costs associated with compliance protocols (e.g., respiratory protection) including some of the ancillary provisions (e.g., medical surveillance, regulated areas).

OSHA has tentatively agreed with the contractor's conservative assessment, which resulted in higher respirator usage than would have been projected if the engineering feasibility assessments which were based on information gathered during OSHA's site visits had been solely relied on. Therefore, OSHA is requesting public comments on the appropriateness of using the contractor's assumptions and estimates. The costs of compliance in the final standard will reflect the information to be received in response to this request.

#### A. Methodology

OSHA's contractor carried out two major data collection activities. The first was intended to gather pertinent secondary data and to help structure the sample frame, and the second was intended to collect primary data from



firms which produce or could potentially use or distribute methylene chloride.

Primary data collection was required to determine current industry practices with regard to control procedures, substitution possibilities, and impacts of the proposed regulation. Primary data were collected from almost 1,300 respondents to a survey questionnaire in 1987. The sample was stratified on the basis of MC application for purposes of survey control and subsequent analysis.

To establish baseline levels of exposure to methylene chloride, CONSAD's subcontractor, PEI Associates, Inc., reviewed inspection or evaluation reports prepared by OSHA, NIOSH, EPA, and the U.S. Air Force (for an EPA survey) in which the use of MC was documented. These reports were

analyzed and grouped according to the application-related taxonomy created for the survey. Exposure data and abstracts of the reports are in the appendices to CONSAD's reports.<sup>1</sup>

#### B. Industry Profile

CONSAD Research Corporation delineated 25 application groups in order to distinguish the different circumstances and processes in which methylene chloride is used. These groups are identified in Table 11. The largest group, cold cleaning, includes 22,652 establishments with 90,293 directly exposed employees. The

<sup>1</sup> Although some of the data were gathered as long ago as the mid-1970s, OSHA believes they are still representative of current exposure levels.

processes employed by this group include wiping with a rag, use of a cold cleaning degreaser, and use of an immersion cleaner. There are also other incidental exposures to methylene chloride. The employees in this group have an estimated arithmetic mean exposure of 26.9 ppm (8-hour TWA). The next largest group, printers, use a solvent (referred to as blanket wash) to clean printing plates and blankets between printing "runs". This group consists of an estimated 10,482 establishments with 34,868 exposed employees. MC-based solvents are used by workers in this group to clean other graphic arts equipment as well. The estimated arithmetic mean exposure for this group is 24.2 ppm (8-hour TWA).

TABLE 11.—METHYLENE CHLORIDE APPLICATION GROUPS

Application group	Estimated number of MC establishments **	Estimated total employment **	Estimated number of exposed workers **	Estimated arithmetic mean of current exposures (PPM)	Estimated MC handled (millions of pounds)
Manufacture of MC .....	6	2,496	124	9.1	467
Distribution/Formulation of Solvents .....	422	110,902	2,245	40.2	250
Metal Cleaning:					
Cold Degreasing and Other Cold Cleaning .....	22,652	860,776	90,293	26.9	31
Open Top Vapor Degreasing .....	124	12,090	271	115.7	7
Conveyorized Vapor Degreasing .....	107	6,942	177	115.7	3
Aerosol Packing .....	217	17,388	2,182	143.3	106
Paint and Paint Remover Formulation:					
Paint Remover Formulation .....	293	22,464	760	23.3	155
Paint Manufacturing .....	390	70,446	1,808	11.7	28
Paint Stripping (PS):					
PS—Large Aircraft Firms .....	75	255,000	1,671	58.1	10
PS—Small Aircraft Firms .....	225	11,826	799	58.1	3
PS—Furniture .....	4,000	21,440	5,720	126.2	14
PS—Industrial .....	1,930	534,803	6,942	70.4	25
Electronics:					
Semiconductors .....	666	608,558	3,888	46.9	1
Printed Circuit Boards .....	393	216,908	832	46.9	39
Foam Blowing/Plastics:					
Foam Blowing .....	180	18,720	1,169	30.1	54
Other Plastics/Adhesives .....	847	288,099	2,546	29.5	10
Ink Use (Printing):					
Ink Solvent Manufacturing .....	37	4,899	143	40.2	9
Ink Solvent Use (Blanket Wash) .....	10,482	174,528	34,868	24.2	9
Pesticide Formulation .....	60	1,440	120	40.2	10
Pharmaceuticals .....	76	49,400	1,007	154.9	28
Solvent Recovery .....	40	1,096	161	3.8	37
Film Base .....	2	46,080	700	35.8	11
Polycarbonates .....	4	1,898	67	3.9	7
Construction .....	9,504	63,115	24,896	57.7	2
Shipyards .....	25	85,212	3,040	139.7	*
Total, all application groups .....	52,757	3,486,526	186,429	40.2	*** 497

\* More than zero, but less than 0.5 million.

\*\* Estimated number of establishments in each application group was based on volume flows of methylene chloride in 1985. Estimated number of establishments was multiplied by total employees per establishment and exposed employees per establishment, as reported in CONSAD's survey.

\*\*\* Netting out rehandling, estimated total consumption equals 467 million pounds manufactured, minus 7 million pounds exported, plus 37 million pounds recovered from used solvent.

Source: CONSAD.

The third largest group, construction, contains 9,504 establishments with 24,896 exposed workers who would be subject to the proposed standards. The

major construction uses of MC are in paint stripping, cleaning of foam heads and equipment, traffic paint, epoxy paint, and adhesives. The estimated

arithmetic mean exposure for construction is 57.7 ppm (8-hour TWA).

The fourth and fifth largest groups use MC-based solvents for paint removal.



The paint stripping-industrial group (1,930 establishments, 6,942 exposed workers) includes paint removal from various surfaces and equipment. This group has a wide variety of alternative paint remover solvents and methods available for metal surfaces. The paint stripping-furniture group (4,000 establishments, 5,720 exposed workers) strips wood and has few, if any, substitutes available which could do the job as quickly or thoroughly or with as little fire hazard as MC. Industrial paint strippers have an estimated arithmetic mean exposure of 70.4 ppm (8-hour TWA). Furniture paint strippers have an estimated arithmetic mean exposure of 126.2 ppm (8-hour TWA). This is the third highest among all of the application groups.

While the above groups constitute the largest in terms of number of establishments, two others are also of special interest: pharmaceuticals and aerosol packing. The pharmaceutical group, with 76 firms and 1,007 exposed workers, has the highest estimated exposure level (154.9 ppm) of any group. The aerosol group has the second highest estimated average exposure level, 143.3 ppm. Activities here include packing of aerosol cans and preparation of batch chemicals. An estimated 217 firms and 2,182 exposed workers are involved.

### C. Technological Feasibility

OSHA has preliminarily determined that both a 50 ppm and a 25 ppm standard are technologically feasible. They can be achieved primarily through the use of engineering controls, supplemented when necessary by air-supplied respirators (ASRs). Local

exhaust ventilation (LEV) is the most typical engineering control; ASRs are the simplest type of respirator which will protect against MC. OSHA notes that NIOSH has determined that MC can break through a cartridge respirator filter in 30 to 45 minutes at 15 ppm.

The assessment of technological feasibility addresses engineering controls as the first step to reduce exposure levels. The primary engineering control for most application groups is local exhaust ventilation. According to PEI Associates, the LEV used in OSHA's model represents good engineering practice for a typical facility in the application group. New LEV can reduce exposures by 80% and incremental LEV (i.e., modifications to existing LEV) can reduce exposures by either 5%, 15%, or 20%, according to the age and design of the original LEV systems in the application groups. The same reduction factors are used in this model for all other types of new and incremental engineering controls, such as general ventilation and booths—with the exception of 50% in printing (because of difficulty in installing LEV on presses) and 50% in construction and shipyards (where portable exhaust or blower units must be used.)

The implementation of LEV and other engineering controls would enable most establishments to reduce the arithmetic mean exposures (AM's) of their exposed workers to or below a target level of one-half of the proposed PELs. Within these establishments, almost all individual exposures would fall below the PELs.

However, in establishments with predicted AMs above the target level

after implementation of engineering controls, some workers would need personal respiratory protection in order to comply with the proposed regulations. OSHA's model adds ASRs for those workers whose exposures cannot be reduced below the PEL with engineering controls. These situations exist for a limited number of establishments in most application groups, even if the predicted AM for the application group is low. PEI has estimated that the ASRs will substantially reduce exposures for those workers who wear them. In order to meet a PEL of 25 ppm, as contrasted to 50 ppm, more workers would have to wear ASRs and the average exposure level under the lower PEL would be lower. Tables 12 and 13 show exposure reductions at the proposed standards.

The technological feasibility analysis shows that in solvent recovery and polycarbonates, engineering controls would not be needed to meet standards of 50 ppm or 25 ppm. In manufacture of MC, controls would be needed for the 25 ppm standard, in order to avoid costs of monitoring. In all other application groups, in order to meet either standard, controls would have to be implemented. In 19 groups for the 50 ppm standard and in 21 groups for the 25 ppm standard, ASRs would be needed for a generally small portion of workers whose exposures could not be brought below the PEL by controls alone.

Tables 14 and 15 show, by application group, the numbers and percents of exposed workers who would be required to wear ASRs in order to meet the proposed standards.

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TABLE 12  
EXPOSURE REDUCTIONS AT 50 PPM STANDARD

Application Group	Total Exposed Workers in Complying Establishments	Reduction Factors		Average Exposures before Regulation (Arithmetic Mean PPM)	Average Exposures after Regulation	
		New Eng'g Controls	Incremental Controls		Engineering Controls Only	Engineering Controls plus Some Use of Respirators
Manufacture of MC	124	n.a.	n.a.	9.14	9.14	9.14
Distribution/Formulation of Solvents	2,021	0.8	0.05	40.18	22.81	21.09
Metal Cleaning						
Cold Degreasing and Other Cold Cleaning	45,147	0.8	0.15	26.88	12.42	12.38
Open Top Vapor Degreasing	244	0.8	0.15	115.70	92.14	49.77
Conveyorized Vapor Degreasing	159	0.8	0.15	115.70	56.52	36.69
Aerosol Packing	1,964	0.8	0.20	143.34	93.35	32.79
Paint and Paint Remover Formulation						
Paint Remover Formulation	684	0.8	0.20	23.34	18.81	18.08
Paint Manufacturing	904	0.8	0.15	11.67	11.34	11.34
Paint Stripping (PS)						
PS - Large Aircraft Firms	836	0.8	0.15	58.13	41.64	29.82
PS - Small Aircraft Firms	400	0.8	0.15	58.13	24.50	16.73
PS - Furniture	5,148	0.8	0.20	126.17	56.58	29.53
PS - Industrial	3,471	0.8	0.20	70.35	32.85	26.96
Electronics						
Semiconductors	3,888	0.8	0.05	46.89	41.59	19.21
Printed Circuit Boards	832	0.8	0.05	46.89	31.91	20.51
Foam Blowing/Plastics						
Foam Blowing	1,169	0.8	0.15	30.10	22.41	18.56
Other Plastics/Adhesives	2,291	0.8	0.15	29.51	22.13	17.03
Ink Use (Printing)						
Ink Solvent Manufacturing	14	0.8	0.05	40.18	22.25	20.72
Ink Solvent Use (Blanket Wash)	3,487	0.5	0.15	24.17	16.66	13.44
Pesticide Formulation	120	0.8	0.20	40.18	30.41	19.86
Pharmaceuticals	1,007	0.8	0.15	154.87	121.68	40.78
Solvent Recovery	161	n.a.	n.a.	3.83	3.83	3.83
Film Base	700	*	*	35.80	*	29.60
Polycarbonates	67	n.a.	n.a.	3.88	3.88	3.88
Construction	19,917	0.8	n.a.	57.68	32.54	17.24
Shipyards	2,432	0.8	n.a.	139.65	119.49	7.26
TOTAL, ALL APPLICATION GROUPS	97,187			40.25	27.83	21.52

\* Exposure reduction for film base was estimated from site visit and establishment data.  
Source: CONRAD



TABLE 13  
EXPOSURE REDUCTIONS AT 25 PPM STANDARD

Application Group	Total Exposed Workers in Complying Establishments	Reduction Factors		Baseline Estimated Group Arithmetic Mean (PPM)	Average Exposures after Regulation	
		New Eng'g Controls	Incremental Controls		Engineering Controls Only	Engineering Controls plus Some Use of Respirators
Manufacture of MC	124	0.8	0.05	9.14	1.75	1.75
Distribution/Formulation of Solvents	2,021	0.8	0.05	40.18	21.72	10.36
Metal Cleaning						
Cold Degreasing and Other Cold Cleaning	45,147	0.8	0.15	26.88	8.67	6.47
Open Top Vapor Degreasing	244	0.8	0.15	115.70	91.15	4.77
Conveyorized Vapor Degreasing	159	0.8	0.15	115.70	54.03	12.15
Aerosol Packing	1,964	0.8	0.20	143.34	93.35	6.32
Paint and Paint Remover Formulation						
Paint Remover Formulation	684	0.8	0.20	23.34	16.19	4.04
Paint Manufacturing	904	0.8	0.15	11.67	9.27	4.01
Paint Stripping (PS)						
PS - Large Aircraft Firms	836	0.8	0.15	58.13	40.50	9.57
PS - Small Aircraft Firms	400	0.8	0.15	58.13	22.18	14.03
PS - Furniture	5,148	0.8	0.20	126.17	55.61	8.40
PS - Industrial	3,471	0.8	0.20	70.35	31.13	7.72
Electronics						
Semiconductors	3,888	0.8	0.05	46.89	41.12	2.60
Printed Circuit Boards	832	0.8	0.05	46.89	30.70	6.64
Foam Blowing/Plastics						
Foam Blowing	1,169	0.8	0.15	30.10	21.86	5.47
Other Plastics/Adhesives	2,291	0.8	0.15	29.51	21.22	4.37
Ink Use (Printing)						
Ink Solvent Manufacturing	14	0.8	0.05	40.18	21.10	10.43
Ink Solvent Use (Blanket Wash)	3,487	0.5	0.15	24.17	13.82	4.29
Pesticide Formulation	120	0.8	0.20	40.18	29.81	2.78
Pharmaceuticals	1,007	0.8	0.15	154.87	121.68	4.54
Solvent Recovery	161	n.a.	n.a.	3.83	3.83	3.83
Film Base	700	*	*	35.80	*	21.54
Polycarbonates	67	n.a.	n.a.	3.88	3.88	3.88
Construction	19,917	0.8	n.a.	57.68	32.13	5.91
Shipyards	2,432	0.8	n.a.	139.65	119.41	2.22
TOTAL, ALL APPLICATION GROUPS	97,187			40.25	25.62	8.15

\* Exposure reduction for film base was estimated from site visit and establishment data.  
Source: CONRAD



TABLE 14  
RESPIRATOR USE AT 50 PPM STANDARD

Application Group	Total Affected Workers	Baseline Estimated Group Arithmetic Mean (PPM)	Number of Workers in ASRs Due to Standard			Percent of Affected Workers in ASRs Due to Standard	Percent of Workyear Exposed to MC	Full-time Equivalent Workers in ASRs Due to Standard	FTE Workers in ASRs Due to Standard as Percent of All Affected Workers
			Due to PEL	Due to STEL	TOTAL				
Manufacture of MC	124	9.14	0	0	0	0.0%	100%	0	0.0%
Distribution/Formulation of Solvents	2,021	40.18	131	0	131	6.5%	45%	59	2.9%
Metal Cleaning									
Cold Degreasing and Other Cold Cleaning	45,147	26.88	145	1	146	0.3%	30%	44	0.1%
Open Top Vapor Degreasing	244	115.70	49	0	49	20.0%	14%	7	2.8%
Conveyorized Vapor Degreasing	159	115.70	25	0	25	16.0%	100%	25	15.7%
Aerosol Packing	1,964	143.34	666	0	667	34.0%	100%	667	34.0%
Paint and Paint Remover Formulation									
Paint Remover Formulation	684	23.34	20	0	20	2.9%	36%	7	1.1%
Paint Manufacturing	904	11.67	0	0	0	0.0%	91%	0	0.0%
Paint Stripping (PS)									
PS - Large Aircraft Firms	836	58.13	57	0	57	6.8%	53%	30	3.6%
PS - Small Aircraft Firms	400	58.13	4	0	4	1.1%	13%	1	0.1%
PS - Furniture	5,148	126.17	1,464	0	1,465	28.5%	20%	293	5.7%
PS - Industrial	3,471	70.35	321	1	322	9.3%	20%	64	1.9%
Electronics									
Semiconductors	3,888	46.89	1,117	0	1,118	28.7%	42%	470	12.1%
Printed Circuit Boards	832	46.89	125	0	125	15.0%	30%	38	4.5%
Foam Blowing/Plastics									
Foam Blowing	1,169	30.10	123	0	123	10.5%	43%	53	4.5%
Other Plastics/Adhesives	2,291	29.51	174	0	174	7.6%	38%	66	2.9%
Ink Use (Printing)									
Ink Solvent Manufacturing	14	40.18	1	0	1	7.1%	13%	0	0.9%
Ink Solvent Use (Blanket Wash)	3,487	24.17	158	3	160	4.6%	11%	18	0.5%
Pesticide Formulation	120	40.18	35	0	35	28.8%	7%	2	2.0%
Pharmaceuticals	1,007	154.87	473	0	473	47.0%	100%	473	47.0%
Solvent Recovery	161	3.83	0	0	0	0.0%	33%	0	0.0%
Film Base	700	35.80	0	0 *	0 *	0.0% *	100%	0 *	0.0% *
Polycarbonates	67	3.88	0	0	0	0.0%	100%	0	0.0%
Construction	19,917	57.68	2,668	0	2,668	13.4%	100%	2,668	13.4%
Shipyards	2,432	139.65	1,769	0	1,769	72.7%	100%	1,769	72.7%
TOTAL, ALL APPLICATION GROUPS	97,187	40.25	9,526	6	9,532	9.8%		6,754	6.9%

\* All exposed workers in film base had ASRs prior to the standard, to deal with short-term excursions.

Source: CONRAD



TABLE 15  
RESPIRATOR USE AT 25 PPM STANDARD

Application Group Application Group	Total Affected Workers	Baseline Estimated Group Arithmetic Mean (PPM)	Number of Workers in ASRs Due to Standard			Percent of Affected Workers in ASRs Due to Standard	Percent of Workyear Exposed to MC	Full-time Equivalent Workers in ASRs Due to Standard	FTE Workers in ASRs Due to Standard as Percent of All Affected Workers
			Due to PEL	Due to STEL	TOTAL				
Manufacture of MC	124	9.14	0	0	0	0.0%	100%	0	0.0%
Distribution/Formulation of Solvents	2,021	40.18	215	0	216	10.7%	45%	97	4.8%
Metal Cleaning									
Cold Degreasing and Other									
Cold Cleaning	45,147	26.88	472	3	475	1.1%	30%	143	0.3%
Open Top Vapor Degreasing	244	115.70	71	0	71	29.0%	14%	10	4.1%
Conveyorized Vapor Degreasing	159	115.70	38	0	38	24.0%	100%	38	23.9%
Aerosol Packing	1,964	143.34	1,215	0	1,215	61.9%	100%	1,215	61.9%
Paint and Paint Remover Formulation									
Paint Remover Formulation	684	23.34	202	0	202	29.5%	36%	73	10.6%
Paint Manufacturing	904	11.67	24	0	25	2.7%	91%	23	2.5%
Paint Stripping (PS)									
PS - Large Aircraft Firms	836	58.13	258	0	258	30.8%	53%	137	16.4%
PS - Small Aircraft Firms	400	58.13	19	0	19	4.6%	13%	2	0.6%
PS - Furniture	5,148	126.17	2,113	0	2,113	41.1%	20%	423	8.2%
PS - Industrial	3,471	70.35	1,118	0	1,118	32.2%	20%	224	6.4%
Electronics									
Semiconductors	3,888	46.89	2,007	0	2,007	51.6%	42%	843	21.7%
Printed Circuit Boards	832	46.89	297	0	297	35.7%	30%	89	10.7%
Foam Blowing/Plastics									
Foam Blowing	1,169	30.10	418	0	418	35.8%	43%	180	15.4%
Other Plastics/Adhesives	2,291	29.51	468	0	468	20.4%	38%	178	7.8%
Ink Use (Printing)									
Ink Solvent Manufacturing	14	40.18	1	0	1	7.1%	13%	0	0.9%
Ink Solvent Use (Blanket Wash)	3,487	24.17	548	1	549	15.8%	11%	60	1.7%
Pesticide Formulation	120	40.18	40	0	40	33.4%	7%	3	2.3%
Pharmaceuticals	1,007	154.87	567	0	567	56.3%	100%	567	56.3%
Solvent Recovery	161	3.83	0	0	0	0.0%	33%	0	0.0%
Film Base	700	35.80	0 *	0 *	0 *	0.0% *	100%	0 *	0.0% *
Polycarbonates	67	3.88	0	0	0	0.0%	100%	0	0.0%
Construction	19,917	57.68	6,876	0	6,876	34.5%	100%	6,876	34.5%
Shipyards	2,432	139.65	2,196	0	2,196	90.3%	100%	2,196	90.3%
TOTAL, ALL APPLICATION GROUPS	97,187	40.25	19,163	6	19,169	19.7%		13,376	13.8%

\* All exposed workers in film base had ASRs prior to the standard, to deal with short-term excursions.  
Source: CONRAD

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The percent of exposed workers in respirators at least part of the time would be above 25% in six application groups at 50 ppm and seven application groups at 25 ppm. These would be shipyards (73% and 90% respectively), pharmaceuticals (47% and 56% respectively), aerosol packing (34% and 62%, respectively), construction (13% and 35%, respectively), semiconductors (29% and 52%, respectively), furniture stripping (29% and 41% respectively), and pesticide formulation (29% and 33%, respectively). In the first four of these groups, exposed workers are estimated to handle MC full-time. In the latter three groups, however, MC is used less than half of the time. On a full-time equivalent (FTE) basis, the percent of exposed workers who would require ASRs drops below 25% in semiconductors, furniture stripping, and pesticides, for either standard.

Overall, under a 50 ppm standard, 9.8% of exposed workers (6.9% FTE) would have to wear respirators. Under a 25 ppm standard, 19.7% of exposed workers (13.8% FTE) would have to wear respirators.

OSHA also considered the technological feasibility of achieving 15-minute short-term exposure limits of five times the proposed PELs—i.e., a STEL of 250 ppm with the 50 ppm standard and a STEL of 125 ppm with the 25 ppm standard. Again, both proposed standards were technologically feasible with the use of LEV, supplemented when necessary by respirators.

#### D. Substitution

OSHA also considered that firms might substitute other solvents for methylene chloride or eliminate products or processes as an alternative to complying with a revised standard.

CONSAD, in consultation with PEI and after considering survey responses, site visit reports, and the views of manufacturers, distributors and users of MC, developed estimates of the percentage of establishments which would substitute away from MC in the event of a revised standard. Five points were chosen to represent the possible gradations of substitution activity: none=0%, minor=10%, some=20%, substantial=50%, near total=90%.

With adoption of a standard of either 50 ppm or 25 ppm, the estimated numbers of workers exposed to MC would drop from the present 186,429 workers in 52,757 establishments to 97,187 workers in 28,147 establishments. In order to avoid costs of compliance, 24,610 establishments would substitute another solvent or abandon products or processes that require MC.

#### E. Total Costs of Regulation

Annualized costs of regulation (including costs of substitution) total \$83 million for all 25 application groups for a 50 ppm standard and \$108 million for a 25 ppm standard.

For either standard, the largest expenses are for engineering controls. Annualized costs of engineering controls are \$43 million for 50 ppm and \$58 million for 25 ppm.\* The next most expensive item is clothing and eye protection, with annual costs of \$14.9 million for either proposed standard. Exposure monitoring has annual costs of \$10.1 million for 50 ppm and \$13.4 million for 25 ppm. (See Tables 16 and 17.)

Furniture paint stripping accounts for the largest share of costs of regulation at either 50 ppm or 25 ppm. These are \$19 million in each year for 50 ppm and \$22 million in each year for 25 ppm. (There are no costs for polycarbonates, since MC is not capable of being released in airborne concentrations either at or above the action level or in excess of the STEL in this application group.)

#### F. Benefits Analysis

The benefits of a revised standard for occupational exposure to MC would include reductions in the incidence of cancer and reductions in acute central nervous system and carboxyhemoglobinemia effects.

TABLE 16.—ANNUALIZED COSTS FOR 50 PPM STANDARD, BY REQUIREMENT

Requirement	Annualized cost (\$000)
Engineering controls:	
Install new controls.....	36,452
Install incremental controls.....	6,717
Subtotal.....	43,169
Monitoring.....	10,101
Air-supplied respirators.....	5,571
Clothing/eye protection.....	14,873
Written compliance program.....	1,057
Medical surveillance.....	3,193
Regulated areas.....	932
Emergency alert device.....	933
Medical recordkeeping.....	42
Exposure recordkeeping.....	213
Total compliance costs.....	80,084
Substitution costs.....	3,356
Grand total.....	83,439

Source: CONSAD.

\* If not annualized, first year capital costs for engineering controls would be \$163 million for 50 ppm and \$219 million for 25 ppm.

Table 17.—ANNUALIZED COSTS FOR 25 PPM STANDARD, BY REQUIREMENT

Requirement	Annualized cost (\$000)
Engineering controls:	
Install new LEV.....	47,132
Install incremental LEV.....	10,517
Subtotal.....	57,649
Monitoring.....	13,385
Air-supplied respirators.....	9,700
Clothing/eye protection.....	14,873
Written compliance program.....	1,916
Medical surveillance.....	4,547
Regulated areas.....	1,731
Emergency alert device.....	933
Medical recordkeeping.....	60
Exposure recordkeeping.....	280
Total compliance costs.....	105,072
Substitution costs.....	3,356
Grand total.....	108,428

Source: CONSAD.

In order to calculate cancer reductions, OSHA began with a multistage model generated by K.S. Crump and Company from animal data. Crump's model predicted an excess risk of cancer at an occupational exposure of 500 ppm for 250 days per year of 45 per 1000 workers over a 45-year period (based on female mice). If the estimated 186,429 workers directly exposed to MC were exposed at the current PEL of 500 ppm, they would suffer 8,147 excess cancer deaths over 45 years.

However, simply applying Crump's model to the current PEL for MC overstates the current population risk. Current average levels of exposure are far lower than the current PEL of 500 ppm.

In order to reflect actual exposure levels, OSHA entered into Crump's model the arithmetic mean exposures for each application group (these ranged from 3.8 ppm for solvent recovery to 154.9 ppm for pharmaceuticals). An estimated 668 cancer deaths over 45 years are projected at the current exposure levels for the currently exposed population.

With the introduction of a new methylene chloride standard, both the number of exposed workers and their levels of exposure would drop. (See Tables 18 and 19.) OSHA estimates that at a PEL of 50 ppm, cancer deaths would be reduced from 668 to 144 over 45 years. This is a reduction of 525 deaths over 45 years, or about 11.7 deaths per year, compared to current levels. A PEL of 25 ppm would further reduce excess cancer deaths to 54 over 45 years, for a total reduction of 614 deaths over 45 years, or about 13.6 deaths per year, compared to current levels.



TABLE 18.—REDUCTIONS IN EXCESS CANCER DEATHS OVER 45 YEARS BY ADOPTING 50 PPM STANDARD

Application group	PELs (PPM)	Exposures current and expected arithmetic mean (PPM)	Directly exposed workers	Expected excess deaths	Reduction in deaths
Manufacture of MC.....	500	9.14	124	0.10	.....
Distribution/Formulation of Solvents.....	50	9.14	124	0.10	0.00
Metal Cleaning.....	500	40.18	2,245	8.04	.....
Cold Degreasing and Other Cold Cleaning.....	50	21.09	2,021	3.80	4.24
Open Top Vapor Degreasing.....	500	26.88	90,293	216.52	.....
Conveyorized Vapor Degreasing.....	50	12.38	45,147	49.89	166.63
Aerosol Packing.....	500	115.70	271	2.79	.....
Paint and Paint Remover Formulation.....	50	49.77	244	1.08	1.71
Paint Remover Formulation.....	500	115.70	177	1.82	.....
Paint Manufacture.....	50	36.79	159	0.52	1.30
Paint Stripping (PS).....	500	143.34	2,182	27.76	.....
PS—Large Aircraft Firms.....	50	32.79	1,964	5.74	22.02
PS—Small Aircraft Firms.....	500	23.34	760	1.58	.....
PS—Furniture.....	50	18.08	684	1.10	0.48
PS—Industrial.....	500	11.67	1,808	1.88	.....
Electronics.....	50	11.34	904	0.92	0.96
Semiconductors.....	500	58.13	1,671	8.65	.....
Printed Circuit Boards.....	50	29.82	836	2.22	6.43
Foam Blowing/Plastics.....	500	58.13	799	4.14	.....
Foam Blowing.....	50	16.73	400	0.60	3.54
Other Plastics/Adhesives.....	500	126.17	5,720	64.11	.....
Ink Use (Printing).....	50	29.53	5,148	13.56	50.55
Ink Solvent Manufacturing.....	500	70.35	7,618	47.72	.....
Ink Solvent Use (Blanket Wash).....	50	26.96	3,809	9.16	38.56
Pesticide Formulation.....	500	46.89	3,888	16.25	.....
Pharmaceuticals.....	50	19.21	3,888	6.67	9.58
Solvent Recovery.....	500	46.89	832	3.48	.....
Film Base.....	50	20.51	832	1.52	1.96
Polycarbonates.....	500	30.10	1,169	3.14	.....
Total, All 23 Application Groups.....	50	18.56	1,169	1.94	1.20
Average Annual Reduction.....	500	29.51	2,546	6.70	.....
.....	50	17.03	2,292	3.48	3.22
.....	500	40.18	143	0.51	.....
.....	50	20.72	14	0.03	0.48
.....	500	24.17	34,868	75.19	.....
.....	50	13.44	3,487	4.18	71.01
.....	500	40.18	120	0.43	.....
.....	50	19.86	120	0.21	0.22
.....	500	154.87	1,007	13.84	.....
.....	50	40.78	1,007	3.66	10.18
.....	500	3.83	161	0.06	.....
.....	50	3.83	161	0.06	0.00
.....	500	35.80	700	2.23	.....
.....	50	29.60	700	1.85	0.38
.....	500	3.88	67	0.02	.....
.....	50	3.88	67	0.02	0.00
.....	500	35.75	159,169	506.97	.....
.....	50	16.74	75,176	112.32	394.65
.....					8.77

Sources: CONSAD, Crump Report, Office of Regulatory Analysis

TABLE 19.—REDUCTIONS IN EXCESS CANCER DEATHS OVER 45 YEARS BY ADOPTING 25 PPM STANDARD

Application group	PELs (PPM)	Exposures current and expected arithmetic mean (PPM)	Directly exposed workers	Expected excess deaths	Reduction in deaths
Manufacture of MC.....	500	9.14	124	0.10	.....
Distribution/Formulation of Solvents.....	25	1.75	124	0.02	0.08
Metal Cleaning.....	500	40.18	2,245	8.04	.....
Cold Degreasing and Other Cold Cleaning.....	25	10.36	2,021	1.87	6.17
Open Top Vapor Degreasing.....	500	26.88	90,293	216.52	.....
Conveyorized Vapor Degreasing.....	25	6.47	45,147	26.08	190.44
.....	500	115.70	271	2.79	.....
.....	25	4.77	244	0.10	2.69
.....	500	115.70	177	1.82	.....



TABLE 19.—REDUCTIONS IN EXCESS CANCER DEATHS OVER 45 YEARS BY ADOPTING 25 PPM STANDARD—Continued

Application group	PELs (PPM)	Exposures current and expected arithmetic mean (PPM)	Directly exposed workers	Expected excess deaths	Reduction in deaths
Aerosol Packing.....	25	12.15	159	0.17	1.65
	500	143.34	2,182	27.76	
	25	6.32	1,964	1.11	26.65
Paint and Paint Remover Formulation.....					
Paint Remover Formulation.....	500	23.34	760	1.58	
	25	4.04	684	0.25	1.33
Paint Manufacture.....	500	11.67	1,808	1.88	
	25	4.01	904	0.32	1.56
Paint Stripping (PS).....					
PS—Large Aircraft Firms.....	500	58.13	1,671	8.65	
	25	9.57	836	0.71	7.94
PS—Small Aircraft Firms.....	500	58.13	799	4.14	
	25	14.03	400	0.50	3.64
PS—Furniture.....	500	126.17	5,720	64.11	
	25	8.40	5,148	3.86	60.25
PS—Industrial.....	500	70.35	7,618	47.72	
	25	7.72	3,809	2.63	45.09
Electronics.....					
Semiconductors.....	500	46.89	3,888	16.25	
	25	2.60	3,888	0.90	15.35
Printed Circuit Boards.....	500	46.89	832	3.48	
	25	6.64	832	0.49	2.99
Foam Blowing/Plastics.....					
Foam Blowing.....	500	30.10	1,169	3.14	
	25	5.47	1,169	0.57	2.57
Other Plastics/Adhesives.....	500	29.51	2,546	6.70	
	25	4.37	2,292	0.89	5.81
Ink Use (Printing).....					
Ink Solvent Manufacturing.....	500	40.18	143	0.51	
	25	10.43	14	0.01	0.50
Ink Solvent Use (Blanket Wash).....	500	24.17	34,868	75.19	
	25	4.29	3,487	1.34	73.85
Pesticide Formulation.....	500	40.18	120	0.43	
	25	2.78	120	0.03	0.40
Pharmaceuticals.....	500	154.87	1,007	13.84	
	25	4.54	1,007	0.41	13.43
Solvent Recovery.....	500	3.83	161	0.06	
	25	3.83	161	0.06	0.00
Film Base.....	500	35.80	700	2.23	
	25	21.54	700	1.35	0.88
Polycarbonates.....	500	3.88	67	0.02	
	25	3.88	67	0.02	0.00
Total, all 21 Application Groups.....	500	35.75	159,169	506.97	
	25	6.51	75,176	43.70	463.27
Average Annual Reduction.....					10.29

Sources: CONRAD, Crump Report, Office of Regulatory Analysis

*G. Economic Impacts*

OSHA calculated economic impacts by comparing estimated substitution or compliance costs of the proposed standards with the estimated sales and profits for affected firms. For most application groups, economic impacts would be modest.

Recurring costs of compliance, even at

25 ppm, will amount to far less than one percent of estimated sales in most application groups. Notable impacts could be experienced, however, by 149 large and small firms which strip paint from aircraft, 80 slab stock foam blowers, and 3,600 firms which strip paint from furniture. In furniture stripping, recurring compliance costs at 50 ppm are estimated to equal 6% of

sales or 106% of profits; at 25 ppm, they are estimated to equal 7% of sales or 121% of profits. (See Tables 20 through 23). It is expected that firms in this category may elect the option to substitute for MC use and/or to specialize in refinishing and send pieces of furniture elsewhere for stripping.

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TABLE 20  
ECONOMIC IMPACT OF A 50 PPM STANDARD - FIRST YEAR

Application Group	Impact of Substitution				Impact of Compliance			
	Number of Establishments Substituting	First Year Substitution Cost per Establishing (\$)	First Year Costs of Substitution		Number of Establishments Complying	First Year Compliance Cost per Establishing (\$)	First Year Costs of Compliance	
			as Percent of Sales	as Percent of Profit			as Percent of Sales	as Percent of Profit
Manufacture of MC	0	-	-	-	6	2,403	0.01%	0.25%
Distribution/Formulation of Solvents	42	0	0.00%	0.00%	380	3,692	0.09%	2.22%
Metal Cleaning								
Cold Degreasing and Other Cold Cleaning	11,326	0	0.00%	0.00%	11,326	1,246	0.02%	0.34%
Open Top Vapor Degreasing	12	12,009	0.15%	3.26%	112	1,330	0.02%	0.36%
Conveyorized Vapor Degreasing	11	18,720	0.24%	5.09%	96	2,087	0.03%	0.57%
Aerosol Packing	22	60,000	0.23%	6.30%	195	7,803	0.03%	0.82%
Paint and Paint Remover Formulation								
Paint Remover Formulation	29	40,000	0.82%	34.00%	264	1,702	0.03%	1.45%
Paint Manufacturing	195	6,000	0.12%	5.10%	195	628	0.01%	0.51%
Paint Remover Use (Paint Stripping)								
Paint Stripping - Large Aircraft Firms	38	5,347	0.00%	0.13%	37	254,902	0.18%	6.21%
Paint Stripping - Small Aircraft Firms	113	852	0.01%	0.31%	112	44,111	0.73%	16.15%
Paint Stripping - Furniture	400	4,075	4.86%	88.44%	3,600	4,889	5.83%	106.08%
Paint Stripping - Industrial	965	1,788	0.02%	0.49%	965	5,434	0.07%	1.48%
Electronics								
Semiconductors	0	-	-	-	666	2,661	0.03%	0.68%
Printed Circuit Boards	0	-	-	-	393	2,285	0.05%	1.07%
Foam Blowing/Plastics								
Foam Blowing	0	-	-	-	180	22,369	0.62%	14.42%
Other Plastics/Adhesives	85	0	0.00%	0.00%	762	1,896	0.05%	1.22%
Ink Use (Printing)								
Ink Solvent Manufacturing	33	0	0.00%	0.00%	4	2,171	0.01%	0.23%
Ink Solvent Use (Blanket Wash)	9,434	0	0.00%	0.00%	1,048	637	0.04%	0.81%
Pesticide Formulation	0	-	-	-	60	1,474	0.02%	0.61%
Pharmaceuticals	0	-	-	-	76	8,219	0.02%	0.37%
Solvent Recovery	0	-	-	-	40	555	0.04%	0.63%
Film Base	0	-	-	-	2	841,099	0.05%	1.55%
Polycarbonates	0	-	-	-	4	0	0.00%	0.00%
Construction	1,901	0	0.00%	0.00%	7,603	1,921	0.43%	11.83%
Shipyards	5	0	0.00%	0.00%	20	31,031	0.10%	2.58%
ALL APPLICATION GROUPS	24,610	311			28,147	2,901		

Source: CONRAD



TABLE 21

## ECONOMIC IMPACT OF A 50 PPM STANDARD - SECOND AND FOLLOWING YEARS

Application Group	Impact of Substitution				Impact of Compliance			
	Number of Establishments Substituting	Recurring Substitution Cost per Establish-ment (\$)	Recurring Costs of Substitution		Number of Establishments Complying	Recurring Compliance Cost per Establish-ment (\$)	Recurring Costs of Compliance	
			as percent of sales	as percent of profit			as percent of sales	as percent of profit
Manufacture of MC	0	-	-	-	6	2,403	0.01%	0.25%
Distribution/Formulation of Solvents	42	0	0.00%	0.00%	380	3,488	0.09%	2.22%
Metal Cleaning								
Cold Degreasing and Other Cold Cleaning	11,326	0	0.00%	0.00%	11,326	1,245	0.02%	0.34%
Open Top Vapor Degreasing	12	0	0.00%	0.00%	112	1,330	0.02%	0.36%
Conveyorized Vapor Degreasing	11	0	0.00%	0.00%	96	2,086	0.03%	0.57%
Aerosol Packing	22	0	0.00%	0.00%	195	7,804	0.03%	0.82%
Paint and Paint Remover Formulation								
Paint Remover Formulation	29	0	0.00%	0.00%	264	1,702	0.03%	1.45%
Paint Manufacturing	195	0	0.00%	0.00%	195	627	0.01%	0.53%
Paint Remover Use (Paint Stripping)								
Paint Stripping - Large Aircraft Firms	38	0	0.00%	0.00%	37	254,902	0.18%	6.21%
Paint Stripping - Small Aircraft Firms	113	0	0.00%	0.00%	112	44,111	0.73%	16.15%
Paint Stripping - Furniture	400	4,075	4.86%	88.44%	3,600	4,889	5.83%	106.08%
Paint Stripping - Industrial	965	1,788	0.02%	0.49%	965	5,434	0.07%	1.48%
Electronics								
Semiconductors	0	-	-	-	666	2,661	0.03%	0.68%
Printed Circuit Boards	0	-	-	-	393	2,285	0.05%	1.07%
Foam Blowing/Plastics								
Foam Blowing	0	-	-	-	180	22,368	0.62%	14.42%
Other Plastics/Adhesives	85	0	0.00%	0.00%	762	1,896	0.05%	1.22%
Ink Use (Printing)								
Ink Solvent Manufacturing	33	0	0.00%	0.00%	4	2,171	0.01%	0.23%
Ink Solvent Use (Blanket Wash)	9,434	0	0.00%	0.00%	1,048	637	0.04%	0.81%
Pesticide Formulation	0	-	-	-	60	1,474	0.02%	0.61%
Pharmaceuticals	0	-	-	-	76	8,219	0.02%	0.37%
Solvent Recovery	0	-	-	-	40	555	0.04%	0.63%
Film Base	0	-	-	-	2	841,256	0.05%	1.55%
Polycarbonates	0	-	-	-	4	0	0.00%	0.00%
Construction	1,901	0	0	0.00%	7,603	1,728	0.39%	10.65%
Shipyards	5	0	0	0.00%	20	30,781	0.10%	2.56%
ALL APPLICATION GROUPS	24,610	136			28,147	2,845		

Source: CONRAD



TABLE 22  
ECONOMIC IMPACT OF A 25 PPM STANDARD - FIRST YEAR

Application Group	Impact of Substitution				Impact of Compliance			
	Number of Establishments Substituting	First Year Substitution Cost per Establishing (\$)	First Year Costs of Substitution		Number of Establishments Complying	First Year Compliance Cost per Establishing (\$)	First Year Costs of Compliance	
			as Percent of Sales	as Percent of Profit			as Percent of Sales	as Percent of Profit
Manufacture of MC	0	-	-	-	6	2,636	0.01%	0.28%
Distribution/Formulation of Solvents	42	0	0.00%	0.00%	380	3,968	0.10%	2.53%
Metal Cleaning								
Cold Degreasing and Other Cold Cleaning	11,326	0	0.00%	0.00%	11,326	1,611	0.02%	0.44%
Open Top Vapor Degreasing	12	15,339	0.20%	4.17%	112	1,699	0.02%	0.46%
Conveyorized Vapor Degreasing	11	21,942	0.28%	5.96%	96	2,446	0.03%	0.66%
Aerosol Packing	22	60,000	0.23%	6.30%	195	9,954	0.04%	1.04%
Paint and Paint Remover Formulation								
Paint Remover Formulation	29	40,000	0.82%	34.00%	264	2,227	0.05%	1.89%
Paint Manufacturing	195	6,000	0.12%	5.10%	195	1,576	0.03%	1.34%
Paint Remover Use (Paint Stripping)								
Paint Stripping - Large Aircraft Firms	38	5,347	0.00%	0.13%	37	361,587	0.26%	8.81%
Paint Stripping - Small Aircraft Firms	113	852	0.01%	0.31%	112	62,618	1.03%	22.93%
Paint Stripping - Furniture	400	4,075	4.86%	88.44%	3,600	5,568	6.64%	120.81%
Paint Stripping - Industrial	965	1,788	0.02%	0.49%	965	6,810	0.09%	1.86%
Electronics								
Semiconductors	0	-	-	-	666	3,182	0.04%	0.81%
Printed Circuit Boards	0	-	-	-	393	2,910	0.07%	1.37%
Foam Blowing/Plastics								
Foam Blowing	0	-	-	-	180	24,300	0.67%	15.67%
Other Plastics/Adhesives	85	0	0.00%	0.00%	762	2,506	0.07%	1.62%
Ink Use (Printing)								
Ink Solvent Manufacturing	33	0	0.00%	0.00%	4	2,494	0.01%	0.26%
Ink Solvent Use (Blanket Wash)	9,434	0	0.00%	0.00%	1,048	911	0.06%	1.16%
Pesticide Formulation	0	-	-	-	60	2,020	0.02%	0.83%
Pharmaceuticals	0	-	-	-	76	8,028	0.02%	0.36%
Solvent Recovery	0	-	-	-	40	555	0.04%	0.63%
Film Base	0	-	-	-	2	1,951,862	0.11%	3.60%
Polycarbonates	0	-	-	-	4	0	0.00%	0.00%
Construction	1,901	0	0.00%	0.00%	7,603	2,663	0.60%	16.41%
Shipyards	5	0	0.00%	0.00%	20	33,824	0.11%	2.81%
ALL APPLICATION GROUPS	24,610	314			28,147	3,770		

Source: CONRAD



TABLE 23  
ECONOMIC IMPACT OF A 75 PPM STANDARD - SECOND AND FOLLOWING YEARS

Application Group	Impact of Substitution				Impact of Compliance			
	Number of Estab- lishments Substi- tuting	Recurring Substitution Cost per Establish- ment (\$)	Recurring Costs of Substitution		Number of Estab- lishments Complying	Recurring Compliance Cost per Establish- ment (\$)	Recurring Costs of Compliance	
			as Percent of Sales	as Percent of Profit			as Percent of Sales	as Percent of Profit
Manufacture of MC	0	-	-	-	6	2,636	0.01%	0.28%
Distribution/Formulation of Solvents	42	0	0.00%	0.00%	380	3,969	0.10%	2.53%
Metal Cleaning								
Cold Degreasing and Other								
Cold Cleaning	11,326	0	0.00%	0.00%	11,326	1,612	0.02%	0.44%
Open Top Vapor Degreasing	12	0	0.00%	0.00%	112	1,698	0.02%	0.46%
Conveyorized Vapor Degreasing	11	0	0.00%	0.00%	96	2,446	0.03%	0.66%
Aerosol Packing	22	0	0.00%	0.00%	195	9,954	0.04%	1.04%
Paint and Paint Remover Formulation								
Paint Remover Formulation	29	0	0.00%	0.00%	264	2,227	0.05%	1.89%
Paint Manufacturing	195	0	0.00%	0.00%	195	1,577	0.03%	1.34%
Paint Remover Use (Paint Stripping)								
Paint Stripping - Large								
Aircraft Firms	38	0	0.00%	0.00%	37	361,586	0.26%	8.81%
Paint Stripping - Small								
Aircraft Firms	113	0	0.00%	0.00%	112	62,618	1.03%	22.93%
Paint Stripping - Furniture	400	4,075	4.86%	88.44%	3,600	5,568	6.64%	120.82%
Paint Stripping - Industrial	965	1,788	0.02%	0.49%	965	6,810	0.09%	1.86%
Electronics								
Semiconductors	0	-	-	-	666	3,182	0.04%	0.81%
Printed Circuit Boards	0	-	-	-	393	2,910	0.07%	1.37%
Foam Blowing/Plastics								
Foam Blowing	0	-	-	-	180	24,300	0.67%	15.67%
Other Plastics/Adhesives	85	0	0.00%	0.00%	762	2,506	0.07%	1.62%
Ink Use (Printing)								
Ink Solvent Manufacturing	33	0	0.00%	0.00%	4	2,495	0.01%	0.26%
Ink Solvent Use (Blanket Wash)	9,434	0	0.00%	0.00%	1,048	910	0.06%	1.16%
Pesticide Formulation	0	-	-	-	60	2,020	0.02%	0.83%
Pharmaceuticals	0	-	-	-	76	8,028	0.02%	0.36%
Solvent Recovery	0	-	-	-	40	555	0.04%	0.63%
Film Base	0	-	-	-	2	1,952,019	0.11%	3.60%
Polycarbonates	0	-	-	-	4	0	0.00%	0.00%
Construction	1,901	0	0.00%	0.00%	7,603	2,524	0.57%	15.56%
Shipyards	5	0	0.00%	0.00%	20	33,605	0.11%	2.79%
ALL APPLICATION GROUPS	24,610	155	0.00%	0.03%	28,147	3,733		

Source: CONRAD

BILLING CODE 4510-26-C



### *H Regulatory Flexibility Analysis*

Among the various application groups, only small firms (those with under 20 total employees) involved with stripping of aircraft or with paint stripping of furniture would incur compliance costs that would threaten their profitability. Small aircraft stripping firms may react by substituting away from MC and by performing more of their work outdoors. Small firms engaged in paint stripping of furniture may react by substituting other chemicals for MC and by specialization. Because almost all firms in this application group are small, the effects would be uniform throughout the group. OSHA invites comments on ways to ameliorate the impacts in these sectors.

### *I. Environmental Impacts.*

Future environmental releases of methylene chloride resulting from the alternative PELs being considered by OSHA will largely be a function of how these alternative PELs affect the demand for methylene chloride and for its substitutes. The demand for methylene chloride has been declining (e.g., generally, it is no longer being used in formulating hairsprays). Any regulatory action by OSHA is expected to further reduce the demand for MC and, thus, the extent of its environmental releases.

The proposed revision of the MC standard is not expected to influence any users of methylene chloride to turn to chlorofluorocarbons as a substitute.

Generally, it is not expected that any significant environmental impact would result from revision of the methylene chloride standard.

### **XI. Environmental Impact**

This section analyzes the impact on the environment of changing the standard for methylene chloride (MC) to either (1) a 50 parts per million (ppm) eight-hour time weighted average permissible exposure limit (PEL) and 250 ppm 15-minute short-term exposure limit (STEL) or (2) a 25 ppm PEL and 125 ppm STEL. It is based on a study conducted for OSHA by CONSAD Research Corporation and reported in *Analysis of Draft Regulatory Standard for Methylene Chloride*, 1990 (Ex. I5).

Current uses of methylene chloride involve releases to the air through venting of storage tanks or drums and performance of activities such as paint stripping and solvent recovery outdoors and also possible air, water, or solid waste pollution in the disposal of waste residues. Additional details by application group are presented in CONSAD's report.

Future environmental releases of methylene chloride resulting from the alternative PELs being considered by OSHA will largely be a function of how these alternative PELs affect the demand for methylene chloride and for its substitutes. The demand for methylene chloride has been declining (e.g., generally, it is no longer being used in formulating hairsprays). Any regulatory action by OSHA is expected to further reduce the demand for MC and thus the extent of its environmental releases.

Although it is technically possible to substitute chlorofluorocarbons (CFCs) for methylene chloride in electronics and foam blowing, OSHA does not expect the proposed revisions of MC standards to have any such effect. CFC products are significantly more expensive than MC products and are themselves being phased out because of their effects on the environment.

To the extent that firms might have to use greater quantities of substitute chemicals to get the same effects formerly obtained with MC, waste residues and disposal costs would increase. On the other hand, increases in MC leak prevention and recycling would improve the environment. Generally, it is not expected that any significant environmental impact would result from revision of the methylene chloride standard.

### **XII. Summary and Explanation of the Proposed Standard**

OSHA believes that the proposed requirements set forth in this notice are those which, based on currently available data, are necessary and appropriate to provide adequate protection to employees exposed to MC. In the development of the proposal, OSHA has considered all recommendations received in response to the ANPR as well as numerous reference works, journal articles, and other data accumulated by OSHA since initiation of this rulemaking.

The language of the standard and the order of the various provisions are consistent with drafting in other recent OSHA health standards, such as the formaldehyde and benzene standards. OSHA believes that a similar style should be followed from standard to standard to facilitate uniformity of interpretation of similar provisions. Section 6(b)(5) of the Act states that health standards shall also be based on "experience gained under this and other health and safety laws."

#### *A. Scope and Application: Paragraph (a)*

This proposed standard would apply to all workplaces in all industries,

including those in general industry, construction and shipyards, where MC is produced, released, stored, handled, used, or transported, and over which OSHA has jurisdiction. As indicated in the following discussion, an exemption provision has been provided in the proposal for those employers who obtain objective data which demonstrate that MC cannot be released from the product in question at concentrations above the action level.

OSHA has consulted with its Shipyard Employment Standards Advisory Committee (SESAC) to obtain information on MC use and exposure in shipyards. On May 13, 1991, OSHA provided the SESAC with the draft proposed regulatory text and with a list of questions. The SESAC formed a work group to generate recommendations regarding the draft proposal and to collect information responsive to OSHA's questions. On August 12, 1991, the work group presented its report to the full committee. In particular, the work group urged OSHA to carefully consider (1) the extent to which the non-positive results of human studies offset the positive results of the animal studies used by OSHA to estimate human cancer risk and (2) the appropriateness of requiring that filter-type respirators not be used by MC-exposed shipyard employees. The work group report also contained information on (1) MC-containing products used in shipyards; (2) the number of shipyard employees exposed to MC; (3) the activities during which shipyard employees are exposed to MC; (4) the measures taken to eliminate or control shipyard employee exposure to MC; and (5) MC exposure levels in shipyards. The SESAC adopted the work group report and forwarded it to OSHA as the recommendation of the Committee (SESAC Tr. 2-82, 8-13-91). The SESAC work group report (Ex. 17a) and the pertinent SESAC meeting transcripts (Ex. 17b) are available for review and copying in the OSHA Docket Office.

In addition, the SESAC discussed whether or not OSHA should allow employers whose employees use MC on fewer than 30 days a year to comply with the draft proposed PELs by any mix of engineering, work practices and respiratory protection. Some SESAC members noted that this threshold would allow small shipyards reasonable flexibility in determining how to comply with the PELs. OSHA solicits comments, supported by cost and benefit data, on this issue and other issues pertaining to shipyards in question 26, above.

As indicated by proposed paragraph (a), OSHA has included construction



within the scope of this rulemaking. Under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) (the Construction Safety Act) and 29 CFR 1911.10, OSHA consults with the Advisory Committee on Construction Safety and Health (ACCSH) in the formulation of standards that would have a significant impact on construction employment. In general, OSHA has complied with these requirements by (1) providing the ACCSH with copies of any draft proposed rule related to construction, along with any pertinent factual information; (2) convening the ACCSH to elicit recommendations on the draft standard; and (3) incorporating the Advisory Committee's recommendations into the notice of proposed rulemaking (NPRM) published in the *Federal Register*, as OSHA deems appropriate, either as proposed regulatory text or as part of the preamble discussion.

OSHA has not yet consulted with the ACCSH regarding the proposed rule for MC because the Committee's members, whose terms expired in June 1990, have not yet been replaced. It is uncertain when the process of reconstituting the ACCSH will be completed.

Based on its review of the rulemaking record, the Agency believes that the NPRM for MC provides the necessary rationale for regulatory action and sets out the requirements needed to protect employees in all industries, including construction, from the health hazards associated with occupational exposure to MC. OSHA believes that further deferral of NPRM publication, pending consultation with the ACCSH, would delay Agency efforts to increase protection of MC-exposed employees, of whom the vast majority work in general industry and in shipyards. Accordingly, OSHA has determined that publishing the MC proposal at this time best effectuates the purposes of the OSH Act.

The Agency will consult the ACCSH and obtain its recommendations regarding the regulation of MC as soon as the ACCSH is in a position to provide its input. If OSHA determines, based on its consultation with the ACCSH, that any provision(s) of the proposal should be revised with respect to the construction industry, the Agency will publish these revisions to the proposal. If the Agency determines, based on consultation with the ACCSH, that it is inappropriate to revise the proposal, OSHA will explain the basis for that determination in the hearing notice.

The notice of proposed rulemaking does not schedule hearings on the proposed rule. OSHA expects to issue a hearing notice, if hearings are requested,

after the Agency has consulted with the ACCSH and has evaluated the Committee's recommendations. This will enable OSHA to conduct a single set of hearings covering all industry sectors where there is occupational exposure to MC.

This section does not apply to the processing, use, and handling of products containing MC where objective data demonstrate that the product cannot release MC above the action level under foreseeable conditions of processing, use, and handling which will cause the greatest possible release. It is likely, in a number of products made from, containing or treated with MC, that an insignificant residual of MC will be present and from which minimal exposure to MC would be expected. This determination (that air concentrations of MC will not exceed the action level or the STEL) need not be based on data generated by the processor but may, for example, be based upon information provided by the manufacturer. The provision enables fabricators or users of products made from, containing or treated with MC to avoid the burdens of compliance with the standard where exposures are minimal.

It should be noted that where objective data are not available to satisfy the conditions for exemption, the employer is required to perform, at the very least, initial monitoring of employee exposures to MC. If the results of initial monitoring indicate employee exposures are below the action level, the employer may discontinue monitoring for those employees and is relieved of other obligations under the proposal, except for the labelling requirements in paragraph (j). Thus, even if operations are not specifically exempted from the proposal, employers have an incentive to keep exposure levels below the 12.5 ppm "action level". This provision has been incorporated in a number of OSHA standards (acrylonitrile 29 CFR 1910.1045, 43 FR 45809 (1978); arsenic 29 CFR 1910.1018, 43 FR 19624 (1978); ethylene oxide 29 CFR 1910.1047, 49 FR 5796 (1984) and 53 FR 11413 (1988)).

In addition, the Hazard Communication Standard, § 1910.1200 (d)(5)(iv), provides that a mixture shall be assumed to pose a health hazard where a component present in the mixture in concentrations of less than one percent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health hazard to employees in those

concentrations. As noted above, OSHA has determined that MC is a potential occupational carcinogen and that there is no MC exposure level at which employees are safe from cancer risk. Therefore, regardless of exposure level, employers whose employees are exposed to MC are required to comply with the requirements of the Hazard Communication Standard.

#### B. Definitions: Paragraph (b)

##### "Action Level"

"Action level" means an airborne concentration of MC at or above 12.5 ppm, measured as an 8-hour time-weighted average. One purpose of the action level is to relieve the burden on employers by providing a cut-off point for virtually all required compliance activities under the proposed standard. In addition, due to the variable nature of employee exposures to airborne concentrations of MC, the concept of an action level provides a means by which the employer may have greater assurance that the employees will not be exposed to MC concentrations above the permissible exposure limits.

The action level also increases the cost-effectiveness and performance orientation of the standard while improving employee protection. Employers who can, in a cost-effective manner, come up with innovative methodology to reduce exposures below the action level, will be encouraged to do so in order to spare themselves the expense of monitoring and medical surveillance. Their employees will be protected because their exposures will be less than half of the permissible exposure limit. When employers do not lower exposures below the action level, employees above the action level will have the protection of medical surveillance, monitoring and other provisions of the standard to give further protection from the effects of MC.

The statistical basis for using an "action level" has been discussed in connection with several other OSHA health standards (see, for example, acrylonitrile (29 CFR 1910.1045 (43 FR 45809, October 3, 1978)). In brief, although all measurements on a given day may fall below the permissible exposure limit, some possibility exists that on unmeasured days the employee's actual exposure may exceed the permissible limit. Where exposure measurements are above the action level, the employer cannot reasonably be confident that the employee may not be overexposed. Therefore, requiring periodic employee exposure measurements to begin at the action



level provides the employer with a reasonable degree of confidence in the results of the exposure measurement program (Ex. 7-248). OSHA's specific choice of setting an action level of one-half the PEL is based on its successful experience in utilizing one-half the PEL as the action level in many standards, such as arsenic, ethylene oxide, vinyl chloride and benzene.

The action level provides a way of maximizing employee protection in those instances where exposures are possibly significant, and of minimizing employer obligations by defining the point below which no action, except as required by the Hazard Communication Standard (29 CFR 1910.1200), is necessary. Use of the action level concept will result in the necessary inclusion of employees under the proposed standard, whose exposures are above the action level and for whom further protection is warranted. The action level concept, therefore, provides an objective means of tailoring different sections of the standard to those employees who are at significant risk of developing adverse health effects from exposure to MC.

"Day" is defined as any part of a calendar day. Therefore, if a requirement is applicable for an employee who is exposed to MC for 10 days in a calendar year, that requirement becomes applicable to an employee who is exposed to MC for any part of each of 10 calendar days in a year.

#### "Emergency"

For the purposes of the standard, an "emergency" is an occurrence such as, but not limited to, equipment failure, rupture of a container, or failure of control equipment which may or does, result in an unexpected significant release of MC. Sections of the proposed standard that include provisions that must be met in case of emergency include Respiratory Protection, Medical Surveillance, Employee Information and Training and Emergency Plan. Every spill or leak does not automatically constitute an emergency situation. The exposure to employees must be high and unexpected. This is a performance-oriented provision which relies on judgment. It is not possible to specify detailed circumstances which constitute an emergency.

"Employee exposure" is defined as that exposure to airborne MC which would occur if the employee were not using respiratory protective equipment. This definition is consistent with OSHA's previous use of the term "employee exposure" in other health standards.

"Methylene chloride" (MC) means an organic compound with chemical formula,  $\text{CH}_2\text{Cl}_2$ . Its Chemical Abstracts Registry Number is 75-09-2. It is a colorless, volatile, liquid with a chloroform-like odor and is not flammable by standard tests in air, but will burn under extreme conditions. It has molecular weight of 84.94, a boiling point of 39.85°C (104°F) at standard atmospheric pressure, a lower explosive limit of 12% and an upper explosive limit of 19.5% in air. It is completely miscible with most organic solvents but is sparingly soluble in water (1.3% by weight at room temperature). It has an extensive oil and fat solubility. Decomposition products during combustion or fire include phosgene, hydrochloric acid and carbon monoxide.

"Regulated area" means an area demarcated by the employer where airborne concentrations of MC exceed or can reasonably be expected to exceed the eight-hour TWA or the STEL. The requirements for regulated areas are discussed in relation to proposed paragraph (e), below.

The definitions of "Assistant Secretary", "Authorized Person" and "Director" are consistent with OSHA's previous uses of these terms found in other health standards.

#### C. Permissible Exposure Limits (PELs): Paragraph (c)

OSHA proposes to set an 8-hour time weighted average (TWA) exposure limit of 25 ppm, because OSHA has determined that occupational exposure to MC at the current 500 ppm 8-hour TWA PEL presents a significant risk of cancer to employees and that compliance with the new standard will substantially reduce that risk.

The basis for the 8-hour permissible exposure limit is discussed above in the sections on significant risk and feasibility. OSHA believes lowering the current PEL to 25 ppm, as an 8-hour TWA, substantially reduces a significant risk and is feasible for industry to achieve.

OSHA is also proposing a short term exposure limit (STEL) of 125 ppm for 15 minutes to protect employees from the acute toxicity of MC and its metabolites, and to complement the protection from MC's carcinogenic effects afforded by compliance with the 8-hour TWA. The acute toxicity of MC is characterized primarily by CNS effects such as, decreased alertness and coordination, headaches and dizziness which may ultimately lead to accidents and further exposure to MC. Without incorporation of a STEL into the MC health standard, an employee can theoretically be exposed to up to 12,000 ppm for one

minute, a level which is regarded as immediately dangerous to life (e.g., loss of orientation or loss of consciousness which could lead to life-threatening accidents or further overexposure to MC).

Another acute toxic effect of MC exposure is the increase in carboxyhemoglobin levels. High carboxyhemoglobin levels can interfere with the oxygen carrying capacity of blood and are a particular problem for individuals who smoke, those who have limited oxygen carrying capacity, those with silent or symptomatic heart disease, and pregnant women.

OSHA is also concerned regarding the metabolism of MC to its putative carcinogenic metabolite. Metabolic evidence suggests that the MFO pathway (the pathway not believed to be a major contributor to carcinogenesis) begins to be saturated at approximately 100 ppm and metabolism by the GST pathway (the putative carcinogenic pathway) becomes more quantitatively important. For this reason, it is important to limit short-term exposure to MC in order to limit metabolism by the GST pathway and protect the employee from excessive exposure to carcinogenic metabolites of MC. A 15-minute STEL of 125 ppm will protect against the CNS effects, maintain the COHb levels below 3% and limit the extent to which MC would be metabolized by the putative carcinogenic pathway, further decreasing the cancer risk. The basis for the STEL is discussed further in the Significance of Risk section, above.

The proposed standard allows a 15-minute exposure to 125 ppm as long as the employer complies with the 8-hour TWA of 25 ppm. If the health effects of MC are related to total dose alone, without regard to temporal distribution of that dose, an 8-hour TWA limit on exposures will reduce the risk of those health effects by limiting the total dose received. However, if the effects from exposure can be shown to be greater when the total dose is received in a short period than when it is spread over a longer period, an 8-hour TWA limit alone might not be adequate to reduce the risks. In the event of such a "dose-rate" relationship being established, a STEL might be warranted as a supplement to the 8-hour TWA in order to provide protection against additional risk attributable to concentration of the dose over short periods. This "dose-rate" relationship has been established for the CNS and COHb acute health effects of MC. The MC metabolic data also suggests a dose rate effect for the carcinogenesis of MC. Because of the



saturation of the MFO pathway described above, the putative carcinogenic pathway becomes quantitatively more important at exposure levels as low as 125 ppm. For this reason, it is prudent to minimize the duration of exposures to MC at 125 ppm. Therefore, a STEL of 125 ppm for 15 minutes duration has been proposed to protect against the dose rate effects described.

The level of the STEL in this proposal, five times the PEL, is consistent with the standards for other substances, such as formaldehyde, which was recently promulgated by OSHA.

#### *D. Exposure Monitoring: Paragraph (d)*

The proposed standard imposes monitoring requirements pursuant to Section 6(b)(7) of the OSH Act (29 U.S.C. § 655) which mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." The purposes of requiring air sampling for employee exposure to MC include: the prevention of overexposure of employees; the determination of the extent of exposure at the work-site; the identification of the source of exposure to MC; and collection of exposure data by which the employer can select the proper control methods to be used and evaluate the effectiveness of the selected methods. Monitoring enables employers to meet the legal obligation of the standard to assure that their employees are not exposed to MC in excess of the prescribed levels, and to be able to notify employees of their exposure levels, as required by section 8(c)(3) of the Act. In addition, collection of exposure monitoring data enables the examining physician to be informed of employee exposure levels.

Exposure monitoring is also important to determine the level of MC to which employees are exposed. This determines what other requirements of the standard will have to be met. Certain sections of the standard are triggered if an employee is exposed above the action level and are not required if the employee is not.

The exposure monitoring provisions require the employer to determine the exposure for each employee exposed to MC. This does not mean that separate measurements for each employee must be taken but rather that "representative employee exposure" is to be determined. In some cases, that will entail monitoring all exposed employees. In others, the monitoring of

"representative" employees suffices. Samples must be taken within the employee's breathing zone (also known as "personal breathing zone samples" or just "personal samples"). The samples used to determine whether the employee is exposed above the action level must represent the employee's exposure to airborne concentrations of MC over an eight-hour period without regard to the use of respirators. Representative 15-minute short-term employee exposures are to be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the STEL for each shift for each job classification in each work area. Here, too, respirators cannot be a factor. (See "Employee exposure", as defined in the definitions section). Full-shift sampling must be conducted for each job classification in each work area. These samples must consist of at least one sample representative of the entire shift or of consecutive samples taken over the length of the shift.

Representative exposure sampling is permitted when there are a number of employees performing essentially the same job under the same conditions. For these types of situations, it may be sufficient to monitor a fraction of such employees in order to obtain data that are "representative" of the remaining employees. As permitted in section (d)(1)(iv), representative personal sampling for employees engaged in similar work and exposed to similar MC levels can be achieved by measuring that member of the exposed group reasonably expected to have the highest exposure. This result would then be attributed to the remaining employees of the group.

To eliminate unnecessary monitoring and improve the cost-effectiveness of the standard, paragraph (d)(1)(iv) allows employers who can document that exposure levels are the same for similar operations in different work shifts throughout the work day, to sample only the shift for which the highest exposures are expected to occur. This provision does not apply to initial monitoring requirements. The employer must be able to demonstrate that employees on the shifts who are not monitored, are not likely to have exposures higher than those of the shifts monitored.

Initial monitoring is required (proposed paragraph (d)(2)) of all employers who have a place of employment covered under the scope of this standard. In addition, the proposed standard requires that the initial monitoring be conducted within 120 days of the effective date of the final standard or the introduction of MC to

the work place. OSHA believes that within that time employers will be able to either prepare objective data exempting them from monitoring requirements or complete initial monitoring.

To eliminate unneeded requirements, proposed paragraph (d)(2)(ii) provides that if an employer has workplace monitoring data from within one year prior to the effective date which satisfies the proposed rule, those data can be used to satisfy the requirements of the initial monitoring. This provision is designed to make clear that OSHA does not intend to require employers who have recently performed appropriate employee monitoring to conduct "initial" monitoring. The employer would use that monitoring data to determine if periodic monitoring was required. If it was required, the recent monitoring data would indicate the appropriate frequency for that monitoring.

The results of the initial monitoring represent the data which would be used to determine when periodic monitoring would be required. The requirements for periodic monitoring are presented in proposed paragraph (d)(3). If exposures are below the action level, no further monitoring would be required unless processes or products change which are likely to lead to higher exposure. If the initial monitoring results show employee exposures at or above the action level, but at or below the PEL, then the employer must repeat monitoring for these individuals every six months. If exposures are above the PEL, then the employer must remonitor every three months. If the employee's exposure is above the STEL, the employer shall repeat such monitoring at least every three months. If, under the terms of proposed paragraph (d)(3)(iv), in subsequent monitoring, results indicate that an employee's exposure, as determined by two consecutive measurements taken at least seven days apart, falls from above the PEL to between the PEL and action level, then monitoring need only be done every six months, unless production changes may lead to higher exposures. Similarly, when the two consecutive measurements indicate that the exposure has dropped below the action level, further monitoring can be discontinued. OSHA believes those frequencies, which are similar to other OSHA standards such as Ethylene Oxide, are sufficient.

OSHA's proposed monitoring of employees whose exposures are between the action level and the 8-hour TWA every six months is based on



several factors. While these employees have been shown to be exposed to levels of MC below the 8-hour TWA, their levels of exposures are not so far below the PEL that monitoring could safely be discontinued. Even minor changes in engineering controls or work practices could result in exposures increasing to levels above the PEL. Remonitoring on a semi-annual basis will enable the employer to be confident that engineering controls are working or, in the event exposures are shown to exceed the 8-hour TWA, alert the employer as to the need for additional controls.

The standard would contain an 8-hour TWA, a STEL and action level. The interrelationship between the 8-hour TWA PEL, the STEL, and the action level at a given workplace would determine the frequency with which employers are obligated to monitor employee exposures under proposed paragraph (d)(3). There would be six possible exposure scenarios, or combinations of 8-hour TWA and short-term exposures, that would determine the frequency of required monitoring. Table 24 below lists these six exposure scenarios, along with their monitoring frequencies. As shown by Table 24, the action level trigger largely determines whether employers must monitor employees exposure to MC. The only exception would be the scenario in which 8-hour TWA exposures are below the action level and short-term exposures are above the STEL. In this particular case, the existence of a STEL would obligate employers to monitor short-term exposures four times per year at those job locations where the STEL was exceeded, but employers would not be obligated to monitor 8-hour TWA exposures at those job locations.

TABLE 24—Six Exposure Scenarios and Their Associated Monitoring Frequencies

Exposure scenario	Required Monitoring Activity
Below the action level and at or below the STEL.	No 8-hour TWA or STEL monitoring required.
Below the action level and above the STEL.	No 8-hour TWA monitoring required; monitor STEL exposures every three months.
At or above the action level, at or below the TWA, and at or below the STEL.	Monitor 8-hour TWA exposures every six months.
At or above the action level, at or below the TWA, and above the STEL.	Monitor 8-hour TWA exposures every six months and monitor STEL exposures every three months.

TABLE 24—Six Exposure Scenarios and Their Associated Monitoring Frequencies—Continued

Exposure scenario	Required Monitoring Activity
Above the TWA and at or below the STEL.	Monitor 8-hour TWA exposures every three months.
Above the TWA and above the STEL.	Monitor 8-hour TWA exposures and STEL exposures every three months.

OSHA recognizes that exposures in the workplace may fluctuate. In the proposed standard, changes in production or work practices which are likely to increase exposure would trigger the provision for additional monitoring. OSHA is concerned that this provision does not provide sufficient guidance to the employer for situations in which the exposure levels may increase without an identifiable change in process or work practice. Currently, the language in the proposal implies that any increase in exposures from between the action level and PEL to above the PEL or STEL would prompt an increased frequency of monitoring. However, in order to eliminate any confusion over the application of this provision, OSHA is considering the addition of a provision to clarify that a periodic exposure monitoring sample which demonstrates that an employee's exposure has increased from below the PEL and STEL to above the PEL or STEL would trigger an increase in the frequency of required monitoring from 6 months to 3 months. This provision would not impose an additional monitoring burden on the employer, but would serve as a clarification of the current proposed requirements. OSHA is soliciting comment as to whether this provision would be necessary and appropriate in the final rule to clarify the intent of the provisions for changing the frequency of monitoring.

Under the terms of proposed paragraph (d)(4) employers are allowed to forgo periodic monitoring of employees for whom initial monitoring results indicate exposure below the action level. Furthermore, if periodic monitoring results indicate, by at least two consecutive measurements taken at least seven days apart, that employee exposures are below the action level, the employer may discontinue monitoring for these employees. OSHA recognizes that monitoring may be a time-consuming, expensive endeavor and therefore offers employers the incentive of being allowed to discontinue monitoring for employees

whose sampling results indicate exposures below the action level. In addition, OSHA anticipates that proposed paragraph (d)(4) will encourage employers to keep exposures to MC below the action level and the STEL in their workplaces. Thus employees would be protected from health hazards and employers could save themselves the time and expense of monitoring and other applicable provisions of the proposed rule as well.

Employees are further protected, even when periodic monitoring has ceased, because additional monitoring is required by paragraph (d)(5)(i) when there has been a process or production change or a change in control equipment, personnel or work practices which may result in new or additional exposures to MC. Additional monitoring is also required when the employer suspects that changes at the workplace will result in new or additional MC exposure. Also, in keeping with Agency policy favoring the use of performance-oriented language, OSHA has proposed the additional monitoring requirement in general terms, instead of trying to define each and every situation where the employer must monitor for new or additional exposures to MC.

Paragraph (d)(5)(ii) specifically requires additional monitoring to be conducted whenever spills, leaks, ruptures or other breakdowns occur. Such occurrences can result in very high exposures. After the clean-up of the spill or repair of the leak employers must again perform the "initial" monitoring provided in proposed paragraph (d)(2) to characterize the exposure for those employees who may be exposed at such areas of their worksites. Such remonitoring provides one method of ascertaining if proper corrective methods have been instituted and if employees' exposures have been significantly altered from what they were prior to the leak or spill.

Under the terms of proposed paragraph (d)(6), the employer is required to use monitoring and analytical methods which have an accuracy (at a confidence level of 95%) of not less than plus or minus 25% for airborne concentrations of MC and within plus or minus 35% over airborne concentrations of MC at the action level. Methods of measurement are presently available to detect MC. One such method is OSHA method 59 which is accurate to 0.029 ppm. Another method is OSHA method 80, which is accurate to 0.201 ppm. Copies of these methods are available from OSHA. Sampling and analysis may also be performed by portable direct reading instruments.



real-time continuous monitoring systems, passive dosimeters or other suitable methods. Employers must select a monitoring method which meets the accuracy and precision requirements of the standard under the unique conditions which exist at the employer's worksite.

Proposed paragraph (d)(7) requires that employers notify affected employees of monitoring results in writing, either individually or by posting of results in an appropriate location accessible to affected employees, within 15 working days after the receipt of the results. In addition, whenever the 8-hour TWA PEL or the STEL has been exceeded, the written notification must contain a description of the corrective action(s) being taken by the employer that will reduce the employee's workplace exposure to or below the PEL and 15 minute STEL. The requirement to inform employees of the corrective actions the employer is going to take to reduce the exposure level to below the PEL is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, in accordance with section 8(c)(3) of the Act.

The employer is also required to allow employees or their designated representatives an opportunity to observe the employee exposure monitoring. This provision is required by section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)). It is provided for in paragraph (l) of the proposal, as is discussed in more detail below.

OSHA solicits comment on the proposed frequency of monitoring and any other aspects of the proposed exposure monitoring requirements.

#### *E. Regulated Areas: Paragraph (e)*

The proposal would require employers to establish a regulated area where airborne exposures to MC exceed either the 8-hour TWA PEL or the STEL. Access to the regulated area would be restricted to authorized persons and the areas themselves are to be designated in a manner that adequately establishes and alerts employees of the boundaries of the regulated areas and minimizes the number of persons exposed to MC within these areas. This provision applies when either the TWA PEL or STEL is likely to be exceeded, but it does not apply to inadvertent releases covered under paragraph (h) (Emergency situations).

The purpose of a regulated area is to ensure that employers make employees aware of the presence of MC at levels above the TWA PEL or STEL in the workplace and to limit MC exposure to as few employees as possible. The

establishment of a regulated area is an effective means of limiting the risk of exposure to substances known to have or suspected of having carcinogenic activity in humans. Because of the serious nature of the possible exposure and the need of persons entering the area to be protected by properly fitted personal protective equipment, such as respirators, the number of persons given access to the area should be limited to only those employees needed to do the job.

In keeping with the performance orientation of this proposed standard, OSHA has not specified how employers are to demarcate their regulated areas. Factors that the Agency believes are appropriate for employers to consider in determining how to demarcate their areas include the configuration of the area, whether the regulated area is permanent, the airborne MC concentration, the number of employees in adjacent areas, and the period of time the area is expected to have exposure levels above the PEL. Permitting employers to choose how to identify and limit access to regulated areas is consistent with OSHA's belief that employers are in the best position to make such a determination based on the specific conditions of their workplaces.

OSHA is proposing to require respirators in regulated areas. As a further means of underscoring the importance of keeping hands and mouth clean from contamination with MC, OSHA is soliciting comment on the appropriateness of prohibiting the following activities in regulated areas: Smoking, eating, drinking, chewing gum or tobacco and applying cosmetics. Because of the health concerns for the metabolism of MC to CO in the body, and the resulting carboxyhemoglobinemia, OSHA feels it is particularly important to exclude smoking (which also produces CO) from regulated areas. OSHA has prohibited the activities listed above in the proposed rule for cadmium (55 FR 4052).

Paragraph (e)(5) requires that an employer at a multi-employer worksite who establishes a regulated area communicate effectively the location and access restrictions to other employers at the worksite. Such communication would lessen the possibility that unauthorized persons would enter the area or that workers not involved in MC-related operations would be exposed inadvertently. OSHA would require employers whose employees are exposed to MC at concentrations above the PELs to be responsible for coordination of their work with other employers whose employees could suffer excessive

exposure because of their proximity to the source of exposure to MC.

The regulated area provision reflects OSHA's concern that the employees at nearby sites be aware of the existence of the hazard and respect the need to remain outside of the perimeters delineated as a regulated area. While this could be accomplished by the employees of the second employer simply reading the signs posted by the first employer, this would not assign accountability. If the second employer is aware of the hazards, then it is the responsibility of the second employer to assure that his employees do not enter the regulated area of the first employer without permission and proper protective equipment.

#### *F. Methods of Compliance: Paragraph (f)*

The proposed standard would require the employer to reduce employee exposures to within the permissible limit by use of feasible engineering controls and work practices. Employers would be required to institute engineering controls and work practices to reduce exposures to the lowest feasible level even if these measures, alone, would not reduce the concentration of airborne MC below the PEL. The employer would be required to supplement these controls with respirators to ensure that employees are not exposed to MC at levels above the PEL.

Primary reliance on engineering controls and work practices is consistent with good industrial hygiene practice and with the Agency's traditional adherence to a hierarchy of preferred controls. However, regarding this traditional hierarchy of controls, OSHA published an advance notice of proposed rulemaking (ANPR) on February 22, 1983 (48 FR 7473) to solicit comments on methods of compliance issues. Among these issues was OSHA's preference for the use of engineering controls over respirators for control of employees' exposures to air contaminants. Many employers have felt the need for increased flexibility in the use of respiratory protection. Based on data received in response to the ANPR, OSHA published a *Federal Register* notice on June 5, 1989, (54 FR 23991) proposing to incorporate additional flexibility in its methods of compliance requirements by more explicitly setting forth circumstances under which respiratory protection may be used due to the general infeasibility of implementing engineering controls. They are: (1) During the time necessary to install feasible engineering controls; (2) Where feasible engineering controls result in only a negligible reduction in



exposures; (3) During emergency, life saving, recovery operations, repair, shutdowns and field situations where there is a lack of utilities for implementing engineering controls; (4) Operations requiring added protection where there is a failure of normal controls; and (5) Entries into unknown atmospheres.

In addition, OSHA requested public comment on other ways of allowing the employer to place greater reliance on the use of respirators to protect workers. Specifically, the Agency asked whether it is necessary to require all feasible engineering controls be installed for maintenance activities; whether respirator use should be permitted for any work situation in which the hazardous exposure is of very brief duration or at any time to achieve compliance with the STEL; and whether respirator use could be allowed in instances where the protection afforded by respirators was equal to, but less costly than, that provided by engineering controls. The proposal also requested information on whether equivalent protection for employees could be achieved by allowing respirator use in lieu of engineering controls for some substances while at the same time requiring employers who choose this option to do something extra, such as submit a written plan to the Agency that demonstrates how respirators provide protection equal to that provided by feasible engineering controls in the given work situation. Finally, OSHA asked for comment on the appropriateness of allowing employers to comply with exposure limits at all times by any method the employer deems advisable, an allowance which would, in effect, abolish OSHA's traditional hierarchy of controls.

In this MC proposal, OSHA would require that employers use engineering controls to comply with the proposed standard, because these controls would reduce exposure hazards in the working environment by removing, at least in part, the contaminant from the air. OSHA has found that employers also generally need to modify their work practices in order to operate engineering controls effectively. OSHA considers the use of respirators to be the least satisfactory approach to exposure control because they provide adequate protection only if employers ensure that respirators are properly fitted and worn. Unlike engineering controls and work practices, respirators are intended to protect only the employees who are wearing them from a hazard, rather than reducing the hazard. Accordingly,

OSHA would permit reliance on respirators only insofar as employers can demonstrate that the engineering controls and work practices needed to comply with the PEL are infeasible.

There are certain activities where exposures are intermittent in nature and limited in duration, most often those involving maintenance and repair operations as well as those in emergency situations, where the use of engineering and work practice controls to control exposure to MC is not feasible. Where engineering controls are not feasible, the employer, nevertheless, has the obligation to protect employees. This obligation may require the use of respirators as a primary means of control.

OSHA policy in the past in this matter has been spelled out in the Respiratory Protection Standard, 29 CFR 1910.134(a)(1), which applies to all exposures to airborne toxicants, and in the Air Contaminant Standard 29 CFR 1910.1000(e), which applies to exposures to all substances listed in Table Z-1, Z-2, and Z-3. This policy was inherent in the national consensus standards which were adopted by OSHA in 1971, pursuant to section 6(a) of the OSH Act of 1970. Subsequent additions to Subpart Z, which were developed through section 6(b) rulemaking proceedings also reflect OSHA's determination that employers must control hazards by engineering controls and work practices instead of respirators to the extent feasible.

Under contract to OSHA, CONSAD conducted a study (Ex. 15) that assessed the type and cost of engineering controls that could be used to meet the proposed PEL. CONSAD's suggested compliance strategy, based on a cost-effectiveness approach, relied primarily on local exhaust ventilation, supplemented when necessary with air supplied respirators. OSHA's proposed standard, however, is performance-oriented so that any combination of engineering controls or work practices may be applied to achieve the PEL; and in certain circumstances, firms may find it appropriate to rely on other measures.

OSHA has described control technologies in Section VI, many of which have already been implemented in certain plants where MC is used. These control strategies include magnetic pumps and magnetic floating gauges, exhausted lances for drum filling, inline quality control sampling equipment, chilling coils and dilution and local exhaust ventilation systems. OSHA solicits information and comments regarding the feasibility and

effectiveness of these compliance strategies.

Employees' exposures also can be controlled with administrative controls. For example, one method of controlling worker exposures to contaminants is by scheduling operations with the highest exposures at a time when the fewest employees are present. However, another form of administrative control, worker rotation, would be prohibited by OSHA as a compliance strategy. Worker rotation reduces the extent of exposure to individual employees, but increases the number of employees exposed. Since MC has been demonstrated to be carcinogenic in animals and is suspected of being carcinogenic to humans, OSHA would prohibit these practices, or any other practice, which would place more employees at risk. Since no threshold has been demonstrated for the carcinogenic action of MC, it is prudent public health practice to limit the number of workers exposed at any concentration. This policy is consistent with language in other recently proposed OSHA standards, such as 1,3-butadiene (55 FR 32736, August 10, 1990) and cadmium (55 FR 4052, February 6, 1990).

Paragraph (f)(2) requires employers who experience exposure in their work places above the PELs to establish and implement a written compliance program which describes the methodology to be used to reduce employee exposure to or below the PELs within their workplaces. No written compliance program is required if the exposure levels are already below the PELs. The written plan must describe the feasible engineering and work practice controls to be implemented, describe any respiratory protection needed to get exposure below the PELs and include a schedule for implementation. The plan would be furnished upon request for examination and copying to OSHA, NIOSH, and affected employees or their representatives. Once a workplace is in compliance with the standard, the written compliance plan need not be updated. If exposures later increase over the PELs, however, an update must be prepared. The written compliance plans are to be revised as appropriate. Circumstances requiring revision of the compliance plan may include a change in controls or substantially different exposure conditions.

#### *G. Respiratory Protection and Other Protective Clothing and Equipment; Paragraph (g)*

*Respiratory Protection:* When engineering controls and work practices



cannot reduce employee exposure to MC to below the PELs, the employer must protect employees' health by the use of respirators. Specifically, respirators must be used while feasible engineering and work practices controls are being installed, in work operations such as maintenance and repair where engineering and work practice control are infeasible and exposures are intermittent and limited in duration, where feasible engineering and work practice controls are not yet sufficient to reduce exposures below the PELs, in regulated areas and in emergencies. These limitations on the required use of respirators are consistent with the requirements of other OSHA health standards (e.g. asbestos, 1910.1001; ethylene oxide 1910.1047; benzene, 1910.1028) and with good industrial hygiene practice. They reflect OSHA's determination, as detailed in the preceding section on methods of compliance, that respirators are inherently less reliable than engineering and work practice controls. OSHA has proposed, therefore, to allow reliance on respirators to control exposures above the PEL only in designated situations.

The proposal requires employers to provide respirators at no cost to the employee and to ensure that employees use the respirators properly. OSHA views this allocation of costs as necessary to effectuate the purposes of the Act. This requirement would make explicit an Agency position which has long been implicit in the promulgation of health standards under section 6(b) of the Act.

The proposal also contains a table (Table 1) listing the types of respiratory protection to be provided based on airborne concentrations of MC in the workplace. The respirator selection table is consistent with OSHA's experience of the performance capabilities of the various types of respirators available. Employers would be allowed to provide respirators with a higher level of protection in lower concentrations of MC.

With the exception of emergency escape situations, OSHA is not allowing the use of air-purifying respirators. NIOSH performed a respirator cartridge breakthrough study with MC (Ex. 7-242) which showed breakthrough times of approximately 40 minutes for cartridges exposed to 15 ppm MC. Because of the short service life of cartridges, NIOSH does not recommend the use of air-purifying respirators for MC. Since the useful service life of cartridges for MC are too short to provide an adequate margin of safety, OSHA is proposing that only supplied air respirators be

allowed for use during exposure to MC above the PELs, with the exception of emergency escape, during which gas masks with organic vapor canisters are allowed. These canisters must be replaced after any emergency use.

NIOSH intends to further study the breakthrough characteristics of MC in organic vapor cartridges and canisters in order to better assess the ability of filter respirators to protect MC-exposed employees. NIOSH expects to have this study completed in time to be considered during this rulemaking. OSHA will closely observe NIOSH's progress on this matter and make available any information gathered during the rulemaking process.

Under proposed paragraph (g)(2), employers shall select respirators from those certified as being acceptable for protection against MC exposure by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH), under the provisions of 30 CFR part 11. NIOSH has proposed the revision of the 30 CFR part 11 respirator certification requirements (52 FR 32401) and their repromulgation as 42 CFR part 84. OSHA is reviewing the NIOSH proposed respirator certification changes, and will be following the progress of the NIOSH's rulemaking on respirator certification.

Under proposed paragraph (g)(3), whenever respirator use is permitted under the proposal to control exposures to MC, the employer must implement a comprehensive respiratory protection program. The protection program must include the elements set forth in the general respiratory protection standard, 29 CFR 1910.134, which contains basic requirements for proper selection, fit, use, training of employees, cleaning, and maintenance of respirators. For employers to ensure that employees use respirators properly, OSHA has found that the employees need to understand the respirator's limits and the hazard it is protecting against in order to appreciate why specific requirements must be followed when respirators are used.

OSHA is currently revising its general respiratory protection standard, and will be updating and expanding the current 29 CFR 1910.134 provisions to account for advances in respiratory protection, fit testing and selection, and other changes in respiratory protection practices since the current standard was adopted in 1971. Since the respiratory protection revision rulemaking and the MC standard revision are taking place concurrently, OSHA is utilizing the respiratory experience gained during the

revision of 29 CFR 1910.134 in preparing the respirator provisions of this MC proposal. OSHA requests comments on all of the respirator provisions in the proposal and their effects on the use of respirators to control exposures to MC.

Under the terms of proposed paragraph (g)(4), employers shall permit employees to leave the regulated area to readjust the respirator facepiece to their faces for proper fit. Employees are also permitted to leave the regulated area to wash their faces to avoid potential skin irritation associated with respirator use.

Proposed paragraph (g)(5) requires initial and annual respirator fit testing when negative pressure respirators are used. A negative pressure is created within the facepiece of a properly fitted respirator when the wearer inhales. A poorly fitted respirator allows contaminated workplace air to enter the facepiece through gaps and leaks in the seal between the face and the facepiece. Employers will be required to perform fit testing in accordance with 29 CFR 1910.134. Qualitative fit testing has been validated by Los Alamos National Laboratory, DuPont, and 3M for protection factors of 10 times the 8-hour TWA, with quantitative fit testing required for higher concentrations. This standard would allow the use of qualitative fit testing for respirators up to an exposure level of 250 ppm of MC (protection factor of  $10 \times 25 \text{ ppm} = 250 \text{ ppm}$ ). In order to use respirators in areas that require higher protection factors, quantitative fit testing must be used.

Proposed paragraph (g)(5)(iii) requires that fit testing follow the protocols in appendix C. Where quantitative fit testing is used, appendix C provides that a fit factor of 10 times the assigned protection factor for that class of respirator must be achieved during the fit test. For example, if the assigned protection factor is 10, a fit factor of 100 must be obtained. These fit factor levels are easily obtainable with tight fitting respirators that properly fit the employee. Respirator fit testing is conducted in a laboratory setting, and experience with fit testing has shown that the quantitative fit factors measured in the test booth do not directly translate to those that would be achieved consistently in the workplace. Therefore, the proposal requires that fit factors of 10 times the assigned protection factor be obtained during quantitative fit testing to better assure that the required levels of protection will be achieved under actual use conditions. Obtaining a proper fit for each employee may require the employer to provide two to three different sizes and types of masks so



that an employee can select the most comfortable respirator having a facepiece with the least leakage around the face seal. After the fit testing has been completed, the employer shall provide and assure that the employee wears the respirator that provides the appropriate protection according to the fit test results.

Once the proper respirator has been selected, a simple facepiece seal fit check performed at the start of each shift by each employee wearing a tight fitting respirator can meet the objective of demonstrating that a proper facepiece seal is being obtained. This test, which is required by 1910.134 (e)(5)(i), can be either a positive pressure fit check, in which the exhalation valve is closed and the wearer exhales into the facepiece to produce a positive pressure, or a negative pressure fit check, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Employees must receive training to perform this test properly.

Proposed paragraph (g)(6) requires that employers provide and ensure the use of the appropriate protective clothing and equipment. Protective clothing used during exposure to MC, such as gloves or aprons, must be resistant to MC. It is the responsibility of the employer to provide protective clothing and equipment at no cost to the employee and to launder, repair, replace and safely dispose of that clothing and equipment. The proposal is sufficiently performance-oriented to allow the employer enough flexibility to provide only the protective clothing and equipment necessary to protect employees in each particular work operation from the MC exposure encountered.

OSHA is aware that many employees may be splashed with MC in the course of occupational exposure. As noted in the Health Effects section, above, "contact with liquid MC is accompanied by an intense burning sensation after a few minutes." Therefore the Agency is considering whether the proposed rule for MC should include requirements for quick-drench showers and eye-wash facilities to protect employees from the potentially serious acute health effects of MC splashes.

When a worker is splashed with MC, the severity of the reaction is determined by the concentration of MC and the length of time it remains in contact with the skin or eyes. The hazard would be reduced by removing the MC from the employee's skin or eyes and by diluting the MC concentration on the employee's skin or clothing. Quick-drench showers that could drench an affected employee with piped-in water

applied with force, and eye-wash facilities that could flush eyes repeatedly with a great amount of water, are already required in the OSHA health standard for formaldehyde (29 CFR 1910.1048(j)). In addition, the health standards for 1,2-dibromo-3-chloropropane (29 CFR 1910.1044(1)), acrylonitrile (29 CFR 1910.1045(m)) and ethylene oxide (29 CFR 1910.1047 (appendix A)) provide for wash and shower facilities to protect employees' eyes and skin from hazards. OSHA discusses its concerns regarding eye and skin effects, gives notice that hygiene facilities may be needed to protect employees from those effects and requests pertinent information in Issue 38, above.

#### *H. Emergency Situations: Paragraph (h)*

Paragraph (h) of OSHA's proposed rule for MC requires that employers develop written plans for emergency situations and that appropriate portions of the plan be implemented in the event of an emergency. The plan must contain a requirement that employees engaged in correcting an emergency situation be provided with appropriate personal protective equipment, such as respiratory protection. Employers must also be prepared to alert employees to evacuate the workplace in the event of an emergency. The performance-oriented language of the proposed paragraph will give employers the flexibility to choose any effective method of alerting employees, including communications systems, voice communication, or a bell or other alarm.

OSHA is proposing specific provisions for emergency situations because of the potential adverse health effects associated with high MC exposures. To clarify that the intent of this provision is to protect employees from unexpected and substantial releases of MC, OSHA has defined "Emergency" as "an occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may result in an unexpected significant release of MC." The types of emergency situations which may be encountered are those which require securing internal or external emergency services such as rescue, fire, or emergency medical services. OSHA recognizes that not all sudden releases constitute emergencies. For example, the accidental breaking of a sampling syringe containing a minute amount of MC would not normally be regarded as an emergency. On the other hand, failure of a valve on a reaction vessel under pressure or failure of a safety relief valve would definitely constitute an emergency.

OSHA believes that compliance with these requirements will ensure that affected employees are substantially protected against exposures which arise in emergency situations.

#### *I. Medical Surveillance: Paragraph (i)*

Section 6(b)(7) of the OSH Act requires that, where appropriate, occupational health standards shall prescribe the type and frequency of medical exams or other tests to be made available, by the employer or at his cost, to exposed employees in order to determine if the employee's health is adversely affected by exposure to workplace hazards.

The purpose of the medical surveillance program for MC is four-fold:

- (1) To determine if an individual can be exposed to the concentration of MC present in his or her workplace without experiencing adverse health effects;
- (2) To detect, to the extent possible, early or mild clinical conditions due to MC exposure so that appropriate preventative measures can be taken;
- (3) To diagnose any occupational diseases that occur as the result of MC exposure; and
- (4) To determine the employee's fitness to use respiratory protective equipment if his or her exposure levels exceed either the PEL or STEL.

The most serious health effect expected from MC exposure is cancer. While the medical surveillance program proposed cannot detect MC-induced cancer at a preneoplastic stage, OSHA anticipates that, as in the past, methods for early detection and treatments leading to increased survival rates will continue to evolve. It is also not presently possible to identify all diseases that may be associated with exposure to MC, so the level of protection afforded the worker by the proposed standard cannot be predicted with any certainty. Thus, an important goal of the medical surveillance program is to provide information on the adequacy of the proposed PELs for MC.

Proposed paragraph (i)(1) specifies the circumstances under which employers must provide medical surveillance for employees exposed to MC. OSHA proposes to require that employers institute a medical surveillance program for all employees exposed to MC at or above the action level for 30 days or more in a year. Medical surveillance would be made available to employees exposed to MC for at least 10 days a year, if their exposure exceeds either of the permissible exposure limits. Appropriate surveillance would also be required to be made available for employees exposed in an emergency



regardless of the airborne concentrations of MC normally present in the workplace. Including such employees within the medical surveillance program ensures that employees, for whom medical surveillance will be of the greatest benefit, will be offered the opportunity to participate.

Inclusion of a cut-off based on duration of exposure recognizes that the most serious diseases associated with MC exposure are chronic diseases, so that employees exposed for only a few days in a year will be at much lower risk of developing MC-related disease. Employers would be able to focus valuable medical surveillance resources on high-risk employees. OSHA believes that the limits placed on medical surveillance by these cutoffs, based both on exposure level and on the number of days an employee is exposed to MC, are reasonable and an administratively convenient way to provide medical surveillance benefits to MC-exposed workers. The proposed cut-offs are also consistent with the approach taken in the promulgated Benzene rule (29 CFR 1910.1028).

In contrast, medical examinations for emergencies are not triggered by airborne concentrations routinely found in a workplace. Where very large amounts of materials are kept in a sealed system, routine exposure may be essentially zero. However, rupture of the container might result in catastrophe. Thus, employers who have identified that they have operations where there is a potential for an emergency involving MC must take necessary actions to assure that, in the event an emergency occurs, facilities will be available and medical assistance by professionals knowledgeable about the toxic effects of MC will be rendered to exposure victims promptly.

The most severe acute effects of MC (narcosis, skin and eye burns at high concentrations) are essentially reversible, even at near fatal exposures. Of course, any acute effects, such as skin burns, narcosis or eye irritation, observed in an employee exposed to MC should be treated.

Employees exposed above the PELs must wear respirators. Should the respirator fail or not be worn as prescribed, the employee may be placed at higher risk. Thus, enhanced surveillance based on level of exposure is a reasonable allocation of scarce medical resources. Employers would also be required to have a physician provide a written opinion establishing the fitness of any employee likely to be required to wear a respirator, regardless of the number of days for which

respirator use is anticipated. This determination would be required before respirator use was implemented and annually thereafter.

Under proposed paragraph (i)(2), and consistent with other recently promulgated standards, including Benzene (29 CFR 1910.1028) and Formaldehyde (29 CFR 1910.1048), OSHA is proposing that all medical procedures be performed by or under the supervision of a licensed physician. Clearly, a licensed physician is the appropriate person to supervise and evaluate a medical examination. However, certain parts of the required examination, such as recording the medical history and drawing blood for blood tests, do not necessarily require the physician's expertise and these may be conducted by other suitably qualified health care personnel under the supervision of the physician.

The proposed requirement that examinations are to be offered without cost to the employee and given at a reasonable time and place and without loss of pay is necessary to ensure that employees will participate in the medical surveillance program. This provision is also consistent with other OSHA health standards and with provisions contained in the OSH Act.

Under proposed paragraph (i)(3), medical examinations and consultations would be provided to employees covered by paragraph (i) as follows: before their initial assignment to work in an area where they would be exposed to MC or within 180 days of the effective date of the MC standard, annually thereafter, upon termination of employment or reassignment to an area where they are no longer exposed to MC at airborne concentrations at or exceeding the action level, and at frequencies other than the above when recommended by the examining physician.

OSHA's requirement for a preplacement examination is intended to achieve the objective of determining if an individual will be able to work with the given MC exposure without adverse effects. It also serves the useful function of establishing a general health baseline for future reference.

OSHA is considering adding a provision in the final rule giving credit to employers for medical examinations performed within one year prior to the effective date of the standard to fulfill the requirements for the initial medical examination. Employers would then be required to offer successive yearly exams at least within one year of the credited exam. OSHA is requesting public comment on the usefulness of

including a provision of this type in the final rule.

The main goal of periodic medical surveillance for workers is to detect adverse health effects at an early, and potentially still reversible stage. Routine screening, occupational and medical histories, and physical examinations must be offered annually for all employees eligible to participate. The interval proposed is consistent with other OSHA health standards. Based on OSHA's experience with these other standards, the Agency believes that annual surveillance would strike a proper balance between the need to diagnose health effects, such as cancer, at an early stage, increasing the possibility of remission through medical intervention, and the limited number of cases likely to be identified through the surveillance program.

To assure that no employee terminates employment while carrying an active, but undiagnosed, disease, OSHA is proposing to require that the employer offer a medical examination to employees when their employment is terminated or when employees are transferred to an area where they would no longer remain eligible for surveillance. OSHA has some concern that this may not be wholly adequate for identifying cancer in high risk employees. Therefore, the Agency requests public comment on whether continued annual surveillance should be offered to employees who have left employment, retired, or transferred to other areas within the employer's operations.

OSHA is also considering the possibility of expanding the proposed medical surveillance to include retirees and presently employed workers who were formerly exposed to MC in previous jobs. Such an approach would be consistent with the requirement in the Benzene standard (29 CFR 1910.1028) which makes medical surveillance available to employees who were exposed to greater than 10 ppm of benzene (the former standard) for 30 or more days in a year prior to the effective date of the standard, when such exposures occurred while the employee worked for his or her current employer. OSHA is seeking comments from the public on whether an expanded medical surveillance program should be included in the final rule and whether any limitations should be imposed on participation in such a program.

Proposed paragraph (i)(4) sets the content for a medical examination. The medical evaluation would include a detailed work and medical history with special emphasis on neurological



symptoms, mental status and cardiac health. This information, collected in the initial exam, would assist the physician in identifying pre-existing conditions that might place the employee at increased risk when exposed to MC. It also establishes a health baseline for future monitoring. In subsequent annual evaluations, changes in neurological symptoms, mental status or cardiac health, in combination with laboratory analyses and information on exposure history, may provide early warnings of MC toxicity.

Laboratory surveillance of employees exposed to MC would include post shift carboxyhemoglobin tests and complete blood count. Because carbon monoxide (CO) is a metabolite of MC, annual post-shift carboxyhemoglobin (COHb) tests would be required for workers exposed to MC. COHb levels greater than 3% can exacerbate angina symptoms, decrease exercise tolerance and increase risks for myocardial infarctions (heart attacks) in susceptible individuals. COHb concentrations can also be used as a rough estimate of worker exposure to MC (taking into consideration smoking behavior and other CO sources) to corroborate personal MC monitoring measurements.

Complete blood count would be used to determine whether an individual is anemic or has an impaired oxygen carrying capacity, and therefore at greater risk for adverse health effects, such as heart attacks, resulting from MC-induced carboxyhemoglobinemia.

Because of the production of CO as a result of MC metabolism and the epidemiological association of solvent exposure and miscarriage, OSHA is proposing to require inclusion of an assessment of the reproductive health of interested employees, especially women. CO has been identified as a risk factor for low birth weight babies and fetal abnormalities (Exs. 7-200, 7-201). Epidemiological evidence has suggested a relationship between occupational exposure to solvents, including MC, and miscarriages (Ex. 7-199). For these reasons, the possibility of adverse reproductive health effects should be assessed by the physician.

The extent and the type of service to be made available to employees who are concerned about their reproductive health would be determined by the examining physician so that affected employees can benefit from new technological developments and the responsible physician can provide services appropriate to the risk to the concerned individual.

In the comments received subsequent to publication of the ANPR for MC (Exs. 10-3, 10-10, 10-28), several industrial

sources indicated that urine analysis, liver function tests and chest X-rays are commonly performed as part of the medical surveillance programs of these companies. OSHA has found no medical justification for annual urine analysis or chest X-ray which is specific for detection of MC-related health effects. Liver function tests have also been evaluated for inclusion as a requirement in the medical surveillance provision. Animal studies and human clinical studies show an association between chronic MC exposure and some indications of liver toxicity. However, this association is only apparent after high doses of MC for prolonged periods of time. The changes in liver function test parameters are not consistent in the human clinical studies and not specific or unique to MC exposure. Therefore, OSHA sees no diagnostic value to requiring annual laboratory analysis of the liver function parameters at this time. OSHA specifically seeks comment on the appropriateness of the three tests described above, that have not been included in the medical surveillance provisions of the proposal. The Agency also seeks medical evidence pertinent to determining if those or other tests should be incorporated into the final rule for MC.

Proposed paragraph (i)(5) allows the medical surveillance examination to be expanded to include any additional tests, examinations, consultations or referrals deemed necessary by the examining physician. This requirement is provided to ensure that adequate flexibility is incorporated into the standard, so that any occupational diseases due to MC exposure are adequately diagnosed and treated.

Under proposed paragraph (i)(6), employers would be required to provide the examining physician, and any specialist involved, with the information needed to assure that they will be adequately informed to reach a medical determination. OSHA is proposing that the employer provide the physician or specialist with a copy of the standard and all relevant appendices. The employer would also be required to supply the physician with information from any previous medical examinations, not otherwise available to the examining physician or specialist.

Proposed paragraph (i)(6) also requires employers to supply the results of exposure monitoring and information on any personal protective equipment and respiratory protection used, or to be used, by the employee to the physician responsible for medical surveillance. A well-documented exposure history assists the physician in determining if a disease that is observed may be related

to MC exposure, and it helps the physician to determine if any restrictions should be placed on the employee's occupational exposure to MC based on medical findings. For employees exposed during emergencies, the employer would be required to supply the physician with a description of the emergency and exposure levels encountered by the employee during the emergency. This information would assist the physician in determining if an employee is likely to be at risk of harmful effects from acute MC exposure.

Proposed paragraph (i)(7) requires employers to obtain from the examining physician a written opinion containing the results of the medical examination with regard to MC exposure, the physician's opinion as to whether the employee would be placed at increased risk of material health impairment as a result of exposure to MC, and any recommended limitations on the employee's exposure or use of personal protective equipment. In rendering an opinion regarding the employee's suitability for work with MC, the physician must rely on the obtained results of clinical and other tests performed to support his or her conclusions.

The physician must exclude findings or diagnoses which are unrelated to MC exposure in the written opinion provided to the employer. OSHA has included this provision to reassure employees participating in medical surveillance that they will not be penalized or embarrassed by the employer's obtaining information about them not directly pertinent to MC exposure. The employee would be informed directly by the physician of all results of his or her medical examination including diseases of a nonoccupational origin.

Also under proposed paragraph (i)(7), employers would be required to provide a copy of the physician's written opinion to the employee within 15 days of receiving the opinion to ensure that the employee has been informed of the results of the medical examination in a timely manner.

#### *J. Communication of Methylene Chloride Hazards to Employees: Paragraph (j)*

In this proposed MC standard, OSHA includes a paragraph entitled: "Communication of methylene chloride hazards to employees." This paragraph addresses the issue of transmitting information to employees about the hazards of MC through the use of: (1) signs and labels, (2) material safety data sheets, and (3) information and training.



Previous OSHA health standards generally included separate paragraphs on employee information and training and signs and labels. This standard incorporates both of those areas into this single paragraph, along with material safety data sheet provisions, to be consistent with the Hazard Communication Standard (HCS) (29 CFR 1910.1200) which addresses these areas.

On November 25, 1983, the Occupational Safety and Health Administration published its final rule on Hazard Communication at 48 FR 53280 and 52 FR 31852. The HCS requires all chemical manufacturers and importers to assess the hazards of the chemicals which they produce or import. It also requires all employers to provide information concerning the hazards of such chemicals to their employees. The transmittal of hazard information to employees is to be accomplished by such means as container labeling and other forms of warning, material safety data sheets and employee training.

Since the HCS "is intended to address comprehensively the issue of evaluating the potential hazard of chemicals and communicating information concerning hazards and appropriate protective measures to employees" (52 FR 31877), OSHA proposes this new paragraph entitled "Communication of Methylene Chloride Hazards to Employees" to avoid repetition of those requirements now comprehensively laid out in § 1910.1200 while specifying additional particular requirements that are needed to protect employees exposed to MC. While avoiding a duplicative administrative burden on those employers attempting to comply with the requirements of several different applicable OSHA health standards, the proposed requirements nevertheless provide the necessary protection for employees through provisions for signs and labels, material safety data sheets, and employee information and training. It should be noted that the communication of MC hazards paragraph of the MC standard has been designed to be substantively as consistent as possible with the HCS requirements for employers. The HCS also addresses the responsibility of producers of chemicals to provide information to downstream employers.

Proposed paragraph (j)(1) requires that regulated areas be posted with signs stating: "Danger, Methylene Chloride, Potential Cancer Hazard, Authorized Personnel Only, Respirators Required in this Area". OSHA intends that the posting of these signs serve as a warning to employees who may otherwise not know they are entering a

regulated area. Such warning signs would be required whenever a regulated area exists, that is, whenever the permissible exposure limit is exceeded. For some work sites, regulated areas exist as a permanent situation, because there is an area where exposures cannot be reduced below the PEL by the use of engineering controls. In those situations, the signs are needed to warn employees not to enter the area unless they are authorized, wearing respirators, and unless there is a need for entering the area.

Regulated areas may also exist on a temporary basis, such as during maintenance and/or emergency situations. The use of warning signs in these types of situations is also important, since a maintenance or emergency situation is by nature a new or unexpected exposure to employees who are regularly scheduled to work at these sites.

These signs are intended to supplement the training which employees are to receive under the other provisions of this paragraph, since even trained employees need to be reminded of the locations of regulated areas and of the precautions necessary to be taken before entering these dangerous areas.

The proposed standard specifies the wording of the warning signs for regulated areas in order to ensure that the proper warning is given to employees. OSHA believes that the use of the word "Danger" is appropriate, based on the evidence of the toxicity and carcinogenicity of MC. "Danger" is used to attract the attention of workers, to alert them to the fact that they are in an area where the permissible exposure limit is exceeded, and to emphasize the importance of the message that follows. The use of the word "Danger" is also consistent with other recent OSHA health standards dealing with carcinogens. The proposed standard also requires that the legend, "Respirators Required in this Area", be included on the warning sign. Regulated areas are defined as areas in which the PEL and STEL are, or are likely to be, exceeded. To ensure that these employees are adequately protected, it is necessary that the sign alert them to the need to wear respirators.

Proposed paragraph (j)(2) requires that warning labels be affixed to all shipping and storage containers containing MC. The labels must state: "Danger, Contains Methylene Chloride, Potential Cancer Hazard". It is proposed that required labels would remain affixed to containers leaving the workplace. The purpose of this requirement is to ensure that all affected

employees, not only those of a particular employer, are apprised to the hazardous nature of MC exposure where exposure could exceed the action level.

In addition to being consistent with the requirements of the HCS, these requirements are consistent with the mandate of section 6(b)(7) of the Act, which requires OSHA health standards to prescribe the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed.

Proposed paragraph (j)(3) requires the employer to obtain or develop and to distribute and provide access to a material safety data sheet for MC in accordance with the requirements of 29 CFR 1910.1200 (g). OSHA feels that a properly completed material safety data sheet (MSDS), if readily available to employees, can serve as an excellent, concise source of information regarding the hazards associated with MC. OSHA's primary intent in this section of the proposed standard, as stated in its recently promulgated HCS, is to ensure that employees will receive as much information as is needed concerning the hazards posed by chemicals in their workplaces. The material safety data sheet ensures that this information will be available to them in a usable, readily accessible and concise form. The material safety data sheet also serves as the central source of information to employees and downstream employers who must be provided with an MSDS if MC or a product containing MC is produced and shipped out of the plant. In addition, the MSDS serves as the basic source of information on the hazards of MC essential to the training provisions of this and other applicable health standards.

Producers and importers have the primary responsibility, under the HCS to develop or prepare the material safety data sheet. The manufacturer or importer is most likely to have the best access to information about the product, and is therefore responsible for disseminating this information to downstream users of the material. For employers whose employees' exposure to MC is from products received from outside sources, the information necessary for a complete MSDS or the MSDS itself is to be obtained from the manufacturer and made available to affected employees. The requirements for the information that is to be contained on the material safety data sheet are explained in detail at 29 CFR 1910.1200(g).

Paragraph (j)(4) of this proposed MC standard requires employers to provide all employees who are exposed to MC



with information and training on MC at the time of initial assignment and at least annually thereafter. A record shall be maintained of the contents of such programs. The training program is to be in accordance with the requirements of the HCS paragraphs (h) (1) and (2), including specific information required to be provided by that section and those items stipulated in the proposed paragraph (j)(4)(iii) of this standard. In addition, employees are to be provided with an explanation of the contents of appendix A (Substance Safety Data Sheet and Technical Guidelines for MC) of the MC standard. Employees are to be informed where a copy of the final MC standard is accessible to them, and receive a description of the medical surveillance program required under proposed paragraph (i). Employees are also to receive an explanation of the purpose of paragraph (i), medical surveillance program, for MC.

OSHA has determined during other rulemakings that an information and training program, as incorporated in this proposed standard in an overall "Communication of Methylene Chloride Hazards to Employees" paragraph, is essential to inform employees of the hazards to which they are exposed and to provide employees with the necessary understanding of the degree to which they themselves can minimize the health hazard potential. As part of an overall communication program for employees, training serves to explain and reinforce the information presented to employees on labels and material safety data sheets. These written forms of information and warning will be successful and relevant only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures thereby reducing the possibility of experiencing adverse health effects. Training is essential to an effective overall hazard communication program. Active employee participation in training sessions can result in the effective communication of hazard information to employees which can further result in workers taking conscientious protective actions at their job duties, thereby decreasing the possibility of occupationally-related illnesses and injuries.

OSHA proposes the training provisions of this standard to be in performance-oriented, rather than specified and detailed language. The proposed standard, in requiring training to be in accordance with the requirements of 29 CFR 1910.1200, lists the categories of information to be transmitted to employees and not the

specific ways that this is to be accomplished. The use of such performance-oriented requirements will encourage employers to tailor their training needs to their specific workplaces, thereby resulting in the most effective training program suitable for each specific workplace.

OSHA believes that the employer is in the best position to determine how the training he or she is providing is being received and absorbed by the employees. OSHA has, therefore, described the objectives to be met and the intent of its training to ensure they can help to protect themselves. The specifics of how this is to be accomplished are left up to the employer.

#### *K. Recordkeeping: Paragraph (k)*

Section 8(c)(3) of the Act provides for the promulgation of "regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." Proposed paragraph (k)(1) requires that employers who rely on objective data in order to gain exemption from the proposed monitoring requirements maintain records that show the basis and reasoning used in reaching the conclusion that the employer should be exempted. In this respect, the objective data substitute for the initial monitoring results. Also, compliance with the requirement to maintain a record of objective data protects the employer at later dates from the contention that initial monitoring was improperly omitted. The employer would be required to maintain the record for the duration of the employer's reliance upon objective data.

Proposed paragraph (k)(2) requires that employers establish and keep an accurate record of all measurements taken to monitor employee exposure to MC. In particular, the proposal requires that employers keep records of the name, social security number, job classification and exposure of each employee represented by monitoring, indicating which employees were actually monitored. In addition, proposed paragraph (k)(3) requires that the employer keep accurate medical records for each employee subject to medical surveillance. Section 8(c) of the Act authorizes the promulgation of regulations requiring an employer to keep necessary and appropriate records regarding activities to permit the enforcement of the Act or to develop information regarding the causes and prevention of occupational illnesses. OSHA has determined that, in this

context, requiring employers to maintain both medical and exposure records (including pulmonary function test results related to respirator use and initial determinations or justifications of exemption from monitoring) is necessary and appropriate. In addition, medical records are necessary for the proper evaluation of the employee's health. Since no purpose is served by long term retention of respirator fit test results (required in mandatory appendix C), OSHA has proposed to require keeping these test results only until the next fit testing.

The proposed standard would require that all required records be made available upon written request to the Assistant Secretary and Director of NIOSH for examination and copying. Access to these records would be necessary for OSHA to monitor compliance. These records also contain information which either of the agencies may need to carry out other statutory responsibilities.

The proposed rule would provide that employees, former employees, and their designated representatives would have access to exposure determinations and records upon request. Section 8(c)(3) of the Act explicitly provides for the promulgation of regulations to "provide employees or their representatives with an opportunity to observe such monitoring or measuring and to have access to the records thereof." Several other provisions of the Act contemplate that employees and their representatives are entitled to have an active role in the enforcement of the Act. Employees and their representatives need the pertinent information concerning exposures to toxic substances and the consequences for the health and safety of the employees if they are to benefit properly from these statutorily created rights.

In addition, proposed paragraph (k) specifies that access to exposure and medical records by employees' designated representatives, NIOSH and OSHA shall be provided in accordance with 29 CFR 1910.20. OSHA promulgated 29 CFR 1910.20 as the generic rule for access to employee exposure and medical records on May 23, 1980 (45 FR 35212). It applies to records created pursuant to specific standards and to records which are voluntarily created by employers. OSHA retains unrestricted access to medical and exposure records but its access to personally identifiable records is subject to the Agency's rules of practice and procedure concerning OSHA access to employee medical records, which have been published at 29 CFR 1913.10. An extensive discussion of the provisions and the rationale for



§ 1910.20 may be found at 45 FR 35312. The discussion of § 1913.10 may be found at 45 FR 35384. It is noted that revisions to the access to records standard are being developed in an ongoing rulemaking proceeding. Proposed paragraph (k) may be affected by any changes which result from that rulemaking effort.

It is necessary to keep records for extended periods of time because of the long latency periods commonly observed for the induction of cancer caused by exposures to carcinogens. Cancer generally cannot be detected until 20 or more years after onset of exposure. The extended record retention period is therefore needed for two purposes. First, possession of past and present exposure data and medical records furthers the diagnosis of workers' ailments. In addition, retaining records for extended periods makes possible a review at some future date of the effectiveness and adequacy of the proposed standard.

The time periods required for retention of exposure records and medical records would be thirty years and the period of employment plus thirty years, respectively. These retention requirements would be consistent with those in the OSHA records access standard and with pertinent sections of the Toxic Substances Control Act.

Proposed paragraph (k)(5) requires employers to comply with the requirements of 29 CFR 910.20(h). That provision requires the employer to notify the Director of NIOSH in writing at least 90 days prior to the disposal of records and to transfer those records to NIOSH unless told not to do so by NIOSH. The employer would be required to comply with any other applicable requirements set forth in the records retention standard.

#### *L. Observation of monitoring: Paragraph (l)*

Section 8(c)(3) of the Act requires that employers provide employees and their representatives with the opportunity to observe monitoring of employee exposures to toxic substances or harmful physical agents. In accordance with this section, the proposal contains provisions for such observation of monitoring of MC exposures.

The observer, whether an employee or a designated representative, must be provided with, and is required to use, any personal protective clothing or equipment required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

#### *M. Date: Paragraph (m)*

As proposed, the final rule would become effective sixty (60) days following publication in the *Federal Register*. OSHA proposes that the requirements for paragraphs (c) through (l) be completed within one-hundred eighty (180) days after the effective date of the final rule, except for provisions for initial monitoring, paragraph (d)(2), and implementation of engineering controls, paragraph (f)(1). Consequently, employers will have 8 months from publication of the standard to accomplish those requirements, which OSHA believes is sufficient time. Initial monitoring (paragraph (d)(2)) shall be completed within one-hundred twenty (120) days from the effective date of the standard. This provision should allow employers sufficient time to complete initial monitoring or prepare objective data exempting them from initial monitoring. Implementation of engineering and work practice controls would be required to be completed no later than one year after the effective date of the standard. This is to allow affected employers sufficient time to design (where necessary), obtain, and install the necessary control equipment. The Agency is soliciting comment on the adequacy of these proposed start-up dates.

#### *N. Appendices: Paragraph (n)*

Three appendices have been included in this proposed standard. Appendices A and B have been included primarily for purposes of information. None of the statements contained therein should be construed as establishing a mandatory requirement not otherwise imposed by the standards, or as detracting from an obligation which the standard does impose. Appendix C, however, is a mandatory appendix, which contains protocols on respiratory fit testing.

The information contained in appendix A is designed to aid the employer in complying with requirements of the standard. The information in appendix B primarily provides information needed by the physician to evaluate the results of the medical examination. It should be noted that paragraph (j) specifically requires that the information contained in appendix A be provided to employees as part of their information and training program. Appendix C contains the "Qualitative and Quantitative Fit Testing Procedures." Proposed paragraph (g)(5)(iii) requires that fit testing be conducted in accordance with appendix C.

#### **XIII. Public Participation**

Interested persons are invited to submit written data, views, and arguments with respect to this proposed standard. These comments must be postmarked on or before April 6, 1992, and submitted in quadruplicate to the Docket Officer, Docket No. H-071, room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Comments limited to 10 pages or less also may be transmitted by facsimile to 202-523-5046 or FTS 8-523-5046, provided the original and three copies are sent to the Docket Office thereafter. Written submissions must clearly identify the provisions of the proposal which are addressed and the position taken with respect to each issue.

The data, views, and arguments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of the proceeding.

#### **XIV. State Plan Applicability**

The 25 states with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of a final standard. These States include: Alaska, Arizona, California, Connecticut (for state and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, Wyoming. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

#### **XV. Authority and Signature**

This document was prepared under the direction of Gerard F. Scannell, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Pursuant to sections 4, 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act (29 U.S.C. 653, 655, 657), section 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); the Secretary of Labor's Order No. 1-90 (55 FR 9033); and 29 CFR part 1911; it is hereby proposed to (1) Amend part 1910 of 29 CFR by adding new § 1910.1052 as set forth below and delete the reference



to MC from Table Z-2 of § 1910.1000, (2) amend part 1915 of 29 CFR by adding new § 1915.1102, and (3) amend part 1926 of 29 CFR by adding new § 1926.61. In addition, pursuant to section 4(b)(2) of the Act, OSHA has determined that this new standard would be more effective than the corresponding standards now in subpart B of part 1910, and in part 1918 of title 29, Code of Federal Regulations. Therefore, any such corresponding standards would be superseded by this new § 1910.1052. This determination, and the application of the new standard to the longshoring industry, would be implemented by adding a new paragraph (m) to § 1910.19.

#### List of Subjects in 29 CFR Part 1910

Methylene chloride, Occupational safety and health, Chemicals, Cancer, Health risk—assessment.

Signed at Washington, DC, this 22nd day of October 1991.

Gerard F. Scannell,

Assistant Secretary of Labor.

#### XVI. Proposed Standard and Appendices

##### General Industry

Part 1910 of title 29 of the Code of Federal Regulations is proposed to be amended as follows:

#### PART 1910—(AMENDED)

##### Subpart B—(Amended)

1. The authority citation for subpart B of part 1910 is revised to read as follows:

Authority: Secs. 4, 6 and 8 of the Occupational Safety and Health Act, 29 U.S.C. 853, 855, 657; Walsh-Healy Act, 29 U.S.C. 35 *et seq.*; Service Contract Act of 1965, 41 U.S.C. 351 *et seq.*; Contract Work Hours and Safety Standards Act (Construction Safety Act) 40 U.S.C. 333; Longshore and Harbor Worker's Compensation Act, 33 U.S.C. 941; National Foundation on Arts and Humanities, 20 U.S.C. 951 *et seq.*; Secretary of Labor's Order 1-90 (55 FR 9033); and 29 CFR part 1911.

2. By adding a new paragraph (m) to § 1910.19 to read as follows:

##### § 1910.19 Special provisions for air contaminants.

(m) Methylene Chloride (MC): Section 1910.1052 shall apply to the exposure of every employee to MC in every employment and place of employment covered by § 1910.16, in lieu of any different standard on exposure to MC which would otherwise be applicable by virtue of that section.

##### Subpart Z—(Amended)

3. The authority citation for subpart Z of 29 CFR part 1910 is revised to read as follows:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, (29 U.S.C. 655, 657). Secretary of Labor's Order No. 1-90 (55 FR 9033); and 29 CFR part 1911.

##### § 1910.1000 [Amended]

4. By removing the entry for "Methylene Chloride from Table Z-2 of § 1910.1000.

5. By adding a new § 1920.1052 to read as follows:

##### § 1910.1052 Methylene chloride.

(a) *Scope and application.* (1) This section applies to all occupational exposures to methylene chloride (MC), Chemical Abstracts Service Registry No. 75-092-2 except as provided in paragraph (a)(2) of this section.

(2) This section does not apply to the processing, use, or handling of products containing MC where objective data are reasonably relied upon that demonstrate that the product or process is not capable of releasing MC in airborne concentrations at or above the action level or in excess of the short-term exposure limit (STEL) under the reasonably foreseeable conditions of processing, use, or handling that will cause the greatest possible release.

(3) Where products containing MC are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in paragraph (k)(1) of this section.

(b) *Definitions:* For the purpose of this section, the following definitions shall apply:

*Action level* means a concentration of airborne MC of 12.5 ppm calculated as an eight-hour time-weighted average.

*Assistant Secretary* means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

*Authorized person* means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (l) of this section, or any other person authorized by the Act or regulations issued under the Act.

*Day* means any part of a calendar day.

*Director* means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

*Emergency* means any occurrence, such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which may or does result in an unexpected significant release of MC (e.g., purging lines or cleaning sludge from tanks).

*Employee exposure* means exposure to airborne MC which would occur if the employee were not using respiratory protection.

*Methylene chloride* (MC) or dichloromethane means an organic compound with chemical formula, CH<sub>2</sub>Cl<sub>2</sub>. Its Chemical Abstracts Registry Number is 75-09-2. Its molecular weight is 84.9 g/mole.

*Regulated area* means any area, demarcated by the employer, where airborne concentrations of MC exceed or can reasonably be expected to exceed a permissible exposure limit, expressed either as an 8-hour time-weighted average exposure or the short-term exposure limit.

(c) *Permissible exposure limits (PELs).* (1) *Eight-hour time-weighted average (TWA) limit:* The employer shall ensure that no employee is exposed to an airborne concentration of MC in excess of twenty-five parts MC per million parts of air (25 ppm) as an eight-hour time-weighted average (8-hour TWA).

(2) *Short-term exposure limit (STEL).* The employer shall ensure that no employee is exposed to an airborne concentration of MC in excess of one hundred and twenty-five parts of MC per million parts of air (125 ppm) as determined over a sampling period of fifteen minutes.

(d) *Exposure monitoring.* (1) *General.* (i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute short-term exposures of each employee.

(ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift for each job classification in each work area.

(iii) Representative 15-minute short-term employee exposures shall be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the STEL for each shift for each job classification in each work area.



(iv) Except for initial monitoring as required under paragraph (d)(2) of this section, where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer need only determine representative employee exposure for that operation during the one shift where the highest exposure is expected.

(2) *Initial monitoring.* (i) Each employer who has a workplace or work operation covered by this section, except as provided for in paragraph (a)(2) of this section, shall perform initial monitoring to determine accurately the airborne concentrations of MC to which employees may be exposed.

(ii) Where the employer has monitored within one year prior to the effective date of this section and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section, provided that the conditions under which the monitoring was conducted remain unchanged.

(3) *Periodic monitoring.* (i) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level but at or below both the 8-hour TWA and the 15-minute STEL, the employer shall repeat such monitoring for each such employee at least every six months.

(ii) If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 8-hour TWA, the employer shall repeat such monitoring for each such employee at least every three months.

(iii) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure above the 15-minute STEL, the employer shall repeat such monitoring for each such individual at least every three months and more often as necessary to evaluate exposures to employees subject to short-term exposures.

(iv) The employer may alter the monitoring schedule from quarterly to semi-annually for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee's exposure has decreased to or below the 8-hour TWA and STEL, but is at or above the action level.

(4) *Termination of monitoring.* (i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be below the action level and at or below the 15-minute STEL, the employer may discontinue the monitoring for those employees who are represented by the

initial monitoring except as otherwise required by paragraph (d)(5) of this section.

(ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level and at or below that STEL, the employer may discontinue the monitoring for those employees who are represented by such monitoring except as otherwise required by paragraph (d)(5) of this section.

(5) *Additional monitoring.* (i) The employer shall institute the exposure monitoring required under paragraphs (d)(2) and (d)(3) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to MC or when the employer has a reasonable suspicion that a change at the workplace may result in new or additional exposures.

(ii) Whenever spills, leaks, ruptures or other breakdowns occur that may lead to employee exposure above the action level or above the STEL, the employer shall repeat the monitoring which is required by paragraph (d)(2)(i) of this section after the clean up of the spill or repair of the leak, rupture or other breakdown.

(6) *Accuracy of monitoring.* Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of MC at or above the 25 ppm 8-hour TWA limit and to within plus or minus 35 percent for airborne concentrations of MC above the action level of 12.5 ppm and below the 25 ppm 8-hour TWA limit.

(7) *Employee notification of monitoring results.* (i) The employer shall, within 15 working days after the receipt of the results of any monitoring performed under this section, notify the affected employee of these results in writing, either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) The written notification required by paragraph (d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the PEL or STEL, wherever monitoring results indicated that the 8-hour TWA or 15-minute STEL has been exceeded.

(e) *Regulated areas.* (1) The employer shall establish a regulated area wherever occupational exposures to airborne concentrations of MC may exceed the permissible exposure limits, either the 8-hour TWA of 25 ppm or 15-minute STEL of 125 ppm.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Each person entering a regulated area shall be supplied with and required to use a respirator, selected in accordance with paragraph (g)(2) of this section.

(4) Regulated areas shall be demarcated from the rest of the workplace in any manner that adequately establishes and alerts employees of the boundaries of the area and minimizes the number of employees exposed to MC within the regulated area.

(5) An employer at a multi-employer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite.

(f) *Methods of compliance.* (1) *Engineering controls and work practices.* (i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the permissible limits, except to the extent that the employer can establish that these controls are not feasible or where paragraph (g)(1) of this section applies.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the PEL or STEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(iii) To the extent feasible, employers shall institute a program to detect leaks and spills. In work areas where spillage may occur, the employer shall make provisions to contain the spill and safely dispose of the waste. The employer shall insure that all leaks are repaired and spills are cleaned promptly by employees wearing appropriate protective equipment and trained in proper methods of cleanup. Compliance with procedures, such as those described in appendix A of this section, would be considered to satisfy this requirement.

(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the PELs.

(2) *Compliance program.* (i) Where the PELs are exceeded, the employer shall establish and implement a written program to reduce employee exposure to or below the PELs by means of engineering and work practice controls, as required by paragraph (f)(1)(i) of this section. To the extent that engineering



and work practice controls cannot reduce exposures to or below the PELs, the compliance program shall provide for the use of respiratory protection.

(ii) The written compliance program shall include a schedule for development and implementation of the engineering controls and work practice controls, including periodic leak detection surveys, and a written plan for emergency situations, as specified in paragraph (h)(1)(i) of this section.

(iii) The written compliance program shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months, and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

(g) *Respiratory protection and other personal protective equipment.* (1) *General.* The employer shall provide respirators, and ensure that they are used, where required by this section. Respirators shall be used in the following circumstances.

(i) During the time interval necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations, such as maintenance and repair activities, vessel cleaning, or other activities for which engineering and work practice controls are demonstrated to be infeasible, and exposures are intermittent in nature and limited in duration;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the PELs; and

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required or allowed under this section, the employer shall select and provide, at no cost to the employee, the appropriate respirator as specified in Table 1, and shall ensure that the employee uses the respirator provided.

(ii) The employer shall select respirators from among those atmosphere supplying respirators approved and certified jointly by the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11. When employers elect to provide gas masks with organic vapor canisters for use in emergency escapes, the organic vapor canisters shall bear the approval of MSHA/NIOSH.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE METHYLENE CHLORIDE

Concentration of airborne methylene chloride or condition of use	Minimum respirator required <sup>1</sup>
Up to 625 ppm.....	(1) Continuous flow supplied air respirator, hood or helmet.
Up to 1250 ppm.....	(1) Full facepiece supplied air respirator operated in negative pressure (demand) mode. (2) Full facepiece self-contained breathing apparatus (SCBA) operated in negative pressure (demand) mode.
Up to 5000 ppm.....	(1) Continuous flow supplied air respirator, full facepiece. (2) Pressure demand supplied air respirator, full facepiece. (3) Positive pressure full facepiece SCBA.
Unknown concentration, or above 5000 ppm.	(1) Positive pressure full facepiece SCBA. (2) Full facepiece pressure demand supplied air respirator with an auxiliary self-contained air supply.
Fire fighting.....	Positive pressure full facepiece SCBA.
Emergency escape.....	(1) Any continuous flow or pressure demand SCBA. (2) Gas mask with organic vapor canister.

<sup>1</sup> Respirators assigned for higher environmental concentrations may be used at the lower concentrations.

(iii) Any employee who cannot wear a negative pressure air-supplied respirator shall be given the option of wearing a respirator with less breathing resistance such as positive pressure SCBA.

(iv) During emergency escape, any employee who cannot wear a negative pressure (organic vapor canister) respirator shall be given the option of wearing a respirator with less breathing resistance, such as a powered air-purifying respirator (PAPR) or SCBA.

(3) *Respirator program.* Where respiratory protection is required by this section, the employer shall institute a respirator program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(4) *Respirator use.* (i) The employer shall permit employees who wear respirators to leave the regulated area to readjust the facepieces to their faces for a proper fit, and to wash their faces and respirator facepieces as necessary in order to prevent skin irritation associated with respirator use.

(ii) Employers who provide gas masks with organic vapor canisters for the purpose of emergency escape shall replace those canisters after any emergency use before they are returned to service.

(5) *Respirator fit testing.* (i) The employer shall assure that each respirator issued to the employee exhibits the least possible facepiece leakage and that the respirator is fitted properly.

(ii) Depending on the MC exposure concentration, the employer shall perform either quantitative or qualitative fit tests at the time of initial fitting and at least annually thereafter for each employee wearing a negative pressure respirator. The test shall be used to select a respirator facepiece which exhibits minimum leakage and provides the required protection as prescribed in Table 1.

(iii) Fit testing shall be conducted in accordance with appendix C of this section.

(6) *Protective Work Clothing and Equipment.* (i) Personal protective clothing and equipment shall be worn where appropriate to prevent eye contact and limit dermal exposure to liquid MC and solutions containing MC. Protective clothing and equipment which is resistant to MC shall be provided by the employer at no cost to the employee and the employer shall assure its use where appropriate. Eye and face protection shall meet the requirements of 29 CFR 1910.133.

(ii) The employer shall provide clean and protective clothing and equipment at least weekly to each affected employee.

(iii) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this paragraph to maintain their effectiveness.

(iv) The employer shall be responsible for the safe disposal of such clothing and equipment. Compliance with such procedures as described in appendix A of this section would be considered to satisfy this requirement.

(h) *Emergency situations.* (1) *Written plan.* (i) A written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with appropriate personal protective equipment, such as respirators.

(2) *Alerting employees.* Where there is the possibility of employee exposure to MC due to an emergency, the employer shall alert each potentially affected employee. If an emergency arises, the employer shall ensure that employees not essential to correcting the situation are immediately evacuated and



restricted from the area, and that normal operations are halted until the emergency is abated.

(i) *Medical surveillance.* (1)

*Employees covered.* (i) The employer shall institute a medical surveillance program for all employees who are or may be exposed to MC concentrations at or above the action level (AL) for at least 30 days a year and for employees who are or may be exposed to MC at or above the 8-hour TWA or above the STEL for at least 10 days a year.

(ii) For any employee required to work in an atmosphere with MC concentrations above the 8-hour TWA or STEL, and therefore required to use a respirator, the employer shall direct the examining physician to ascertain the employee's ability to wear a respirator and, for employees who are able to wear respirators, provide a written opinion to the employer stating that fact.

(iii) The employer shall make medical surveillance available for all employees exposed to MC during an emergency.

(2) *Examination by a physician.* All medical procedures shall be performed by or under the supervision of a licensed physician and all laboratory tests are to be conducted by an accredited laboratory. All examinations and diagnostic procedures shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(3) *Frequency of examinations.* The employer shall make available medical examinations and consultations to each employee covered under paragraph (i)(1) of this section on the following schedules:

(i) Within 180 days of the effective date of this section, or before the time of initial assignment of the employee, whichever is last.

(ii) Annually.

(iii) At termination of employment or reassignment to an area where exposure to MC is consistently below the action level, if three months or more have elapsed since the last medical examination.

(iv) At frequencies other than the above when recommended in the physician's written opinion.

(4) *Content of Medical Examination.* Medical examinations made available pursuant to paragraph (i)(3) of this section shall include, at a minimum:

(i) A comprehensive or interim (from time of last exam) medical and work history with special emphasis on neurological symptoms, mental status, and cardiac health.

(ii) Physical examination giving particular attention to the lungs, liver, nervous system, and breast.

(iii) Laboratory surveillance including carboxyhemoglobin levels and a complete blood count.

(iv) Determination of any reproductive difficulties, such as miscarriages and inability to conceive.

(v) Any additional information determined by the examining physician to be necessary to provide an appropriate assessment.

(5) *Additional examinations and referrals.* Where the examining physician determines it is necessary, the scope of the medical examination shall be expanded and the appropriate referrals, consultation or additional medical surveillance services shall be provided.

(6) *Information provided to the physician.* The employer shall provide the following information to the examining physician and to any specialist involved in the diagnosis:

(i) A copy of this section including its appendices;

(ii) A description of the affected employee's past, current and anticipated future duties as they relate to the employee's MC exposure;

(iii) The employee's former or current exposure levels or, for employees not yet occupationally exposed to MC, the employee's anticipated exposure levels and the frequency and exposure levels of abnormal events (i.e., emergencies);

(iv) A description of any personal protective equipment, such as respirators, used or to be used; and

(v) Information from previous employment-related medical examinations of the affected employee which is not otherwise available to the examining physician or the specialist.

(7) *Physician's written opinion.* (i) For each examination required by this section, the employer shall obtain and provide the employee with a copy of the examining physician's written opinion within 15 days of the examination. The written opinion shall be limited to the following information:

(A) The results of any tests or related evaluation concerning MC exposure carried out as part of the medical evaluation;

(B) The physician's opinion concerning whether the employee has any detected medical condition(s) which would place the employee's health at increased risk of material impairment from exposure to MC. Clinical and other test results shall be used by the physician to support any findings and recommendations.

(C) Any recommended limitations upon the employee's exposure to MC or upon the employee's use of protective clothing or equipment and respirators;

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from MC exposure which require further explanation or treatment.

(ii) The employer shall instruct the physician not to reveal to the employer, orally or in the written opinion, any specific records, findings, and diagnoses that have no bearing on occupational exposures to MC.

(j) *Communication of methylene chloride hazards to employees.*

(1) *Warning Signs.* (i) Warning signs shall be provided and displayed in regulated areas. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective steps before entering the area.

(ii) The warning signs required by paragraph (j)(1)(i) of this standard shall comply with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200(f) (general industry), 29 CFR 1915.99(f) (shipyard employment) and 29 CFR 1926.59(f) (construction industry) and shall bear the following information.

DANGER  
METHYLENE CHLORIDE  
POTENTIAL CANCER HAZARD  
AUTHORIZED PERSONNEL ONLY  
RESPIRATORS REQUIRED IN THIS AREA

(2) *Warning Labels.* (i) Shipping and storage containers containing MC, shall bear appropriate warning labels, as specified in paragraph (j)(2)(ii) of this section.

(ii) The labels shall comply with the requirements of the Hazard Communication Standard 29 CFR 1910.1200(f) (general industry), 29 CFR 1915.99(f) (shipyard employment) and 29 CFR 1926.59(f) (construction industry) and shall include the following information:

DANGER  
CONTAINS METHYLENE CHLORIDE  
POTENTIAL CANCER HAZARD

(3) *Material safety data sheets.* Employers who are manufacturers or importers of MC shall comply with the requirements regarding development and distribution of material safety data sheets as specified in 29 CFR 1910.1200(g) of OSHA's Hazard Communication Standard. All employers with employees potentially exposed to



MC shall maintain material safety data sheets and provide their employees with access to them, in accordance with the requirements of 29 CFR 1910.1200(g) and 29 CFR 1926.59(g).

(4) *Employee information and training.* Employers shall provide each employee with information and training in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200(h) (general industry), and 29 CFR 1926.59(h) (construction industry). In addition:

(i) The employer shall institute a training program for all employees who are potentially exposed to MC at or above the action level or the STEL, assure employee participation in the program and maintain a record of the contents of such program.

(ii) Training shall be provided prior to or at the time of initial assignment to a job potentially involving exposure to MC and at least annually thereafter.

(iii) The training program shall be conducted in a manner that the employee is able to understand. The employer shall assure that each employee is informed of the following:

(A) The health hazards associated with MC exposure, with special attention to the information incorporated in appendix A;

(B) The quantity, location, manner of use, release, and storage of MC and the specific nature of operations that could result in exposure to MC, especially exposures above the 8-hour TWA or STEL;

(C) The engineering controls and work practices associated with the employee's job assignment;

(D) The measures employees can take to protect themselves from exposure to MC, including modification of their habits, such as smoking and personal hygiene;

(E) Specific procedures the employer has implemented to protect employees from exposure to MC, such as appropriate work practices, emergency procedures, and personal protective equipment;

(F) The details of the hazard communication program developed by the employer, including an explanation of the signs, labeling system and material safety data sheets, and how employees can obtain and use the appropriate hazard information;

(G) The purpose, proper selection, fitting, proper use, and limitations of respirators and protective clothing;

(H) The purpose and a description of the medical surveillance program required by paragraph (i) of this section;

(I) The contents of this standard and its appendices, and

(J) The right of any employee exposed to MC at or above the action level or above the STEL to obtain:

(1) Medical examinations as required by paragraph (i) of this section at no cost to the employee;

(2) The employee's medical records required to be maintained by paragraph (k)(3) of this section;

(3) All air monitoring results representing the employee's exposure to MC and required to be kept by paragraph (k)(2) of this section.

(iv) The employer shall make a copy of this standard and its appendices readily available without cost to all affected employees and shall provide a copy if requested.

(v) The employer shall provide to the Assistant Secretary or the Director, upon request, all materials relating to the employee information and training program.

(k) *Recordkeeping.* (1) *Objective data for exempted operations.* (i) Where an employer seeks to demonstrate through reasonable reliance on objective data that any materials in the workplace containing MC will not release MC at levels meeting or exceeding the action level or the STEL under foreseeable conditions of exposure, the employer shall establish and maintain an accurate record of the objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of MC;

(D) A description of the operation exempted and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) *Exposure measurements.* (i) The employer shall establish and keep an accurate record of all measurements taken to monitor employee exposure to MC as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation involving exposure to MC which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of personal protective equipment, such as respiratory protective devices, worn, if any; and

(F) Name, social security number, job classification and exposure of all of the employees represented by monitoring, indicating which employees were actually monitored.

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.20.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under paragraph (i)(1)(i) of this section.

(ii) The record shall include at least the following information:

(A) The name, social security number and description of the duties of the employee;

(B) Physicians' written opinions;

(C) Any employee medical complaints related to exposure to MC; and

(D) A copy of the information provided to the physician as required by paragraph (i)(6) of this section.

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.20.

(4) *Respirator fit testing.* (i) The employer shall establish and maintain accurate records for each employee subject to negative pressure fit testing required by this section.

(ii) This record shall include:

(A) A copy of the protocol selected for respirator fit testing.

(B) A copy of the results of any quantitative fit testing performed.

(C) The size and manufacturer of the types of respirators available for selection.

(D) The date of the most recent fit testing, the name and social security number of the tested employee, and the respirator type and facepiece selected.

(iii) Respirator fit testing records shall be kept until replaced by a more recent record.

(5) *Availability.* (i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying in accordance with 29 CFR 1910.20.

(ii) The employer, upon request, shall make any records required by paragraphs (k)(1) and (k)(2) of this section available for examination and copying by affected employees, former employees, designated representatives.

(iii) The employer, upon request, shall make employee medical records required to be kept by paragraph (k)(3)



of this section available for examination and copying by the subject employee and by anyone having the specific written consent of the subject employee.

(6) *Transfer of records.* The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.20(h).

(l) *Observation of monitoring.* (1) *Employee observation.* The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to MC conducted in accordance with paragraph (d) of this section.

(2) *Observation procedures.* When observation of the monitoring of employee exposure to MC requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with and the observer shall be required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

(m) *Dates* (1) *Effective date.* This section shall become effective sixty (60) days after the date of publishing the final standard in the Federal Register.

(2) *Start-up dates.* (i) The requirements of paragraphs (c) through (l) of this section, including feasible work practice controls but not including initial monitoring as required by paragraph (d)(2) and engineering controls specified in paragraph (f)(1), shall be complied with within one-hundred and eighty (180) days after the effective date of this section.

(ii) Initial monitoring required by paragraph (d)(2) shall be completed within 120 days after the effective date of this section or the introduction of MC into the workplace.

(iii) Engineering controls specified by paragraph (f)(1) of this section shall be implemented within one (1) year after the effective date of this section.

(n) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation. The protocols on respiratory fit testing in appendix C are mandatory. Appendix C will be codified in the final rule.

## Appendix A to § 1910.1052—Substance Safety Data Sheet and Technical Guidelines for Methylene Chloride

### I. Substance Identification

A. Substance: Methylene chloride ( $\text{CH}_2\text{Cl}_2$ ).  
B. Synonyms: Dichloromethane (DCM); Methylene dichloride; Methylene bichloride; Methane dichloride; CAS-75-09-2; NCI-C50102.

### C. Physical data:

1. Molecular weight: 84.9
2. Boiling point (760 mm Hg.): 39.8 °C (104 °F).
3. Specific gravity (water=1): 1.3
4. Vapor density (air=1 at boiling points): 2.9
5. Vapor pressure at 20 °C (68 °F): 350 mm Hg
6. Solubility in water, g/100 g water at 20 °C (68 °F)=1.32.
7. Appearance and odor: colorless liquid with a chloroform-like odor.

D. Uses: MC is used as a solvent, especially where high volatility is required. It is a good solvent for oils, fats, waxes, resins, bitumen, rubber and cellulose acetate and is a useful paint stripper and degreaser. It is used in paint removers, in propellant mixtures for aerosol containers, as a solvent for plastics, as a degreasing agent, as an extracting agent in pharmaceutical industry and as a blowing agent in polyurethane foams. Its solvent property is sometimes increased by mixing with methanol, petroleum naphtha or tetrachloroethylene.

E. Appearance and odor: MC is a clear colorless liquid with a chloroform-like odor. It is slightly soluble in water and completely miscible with most organic solvents.

F. Permissible exposure: Exposure may not exceed 25 parts MC per million parts of air (25 ppm) as an eight-hour time-weighted average (8-hour TWA), short-term exposure limit (STEL) may not exceed 125 parts of MC per million parts of air (125 ppm) averaged over a 15-minute period.

### II. Health Hazard Data

A. MC can affect the body if it is inhaled or if the liquid comes in contact with the eyes or skin. It can also affect the body if it is swallowed. Employers shall advise employees of all areas and operations where exposure to MC occurs.

#### B. Effect of overexposure:

1. Short-term Exposure: MC is an anesthetic. Inhaling the vapor may cause mental confusion, light-headedness, nausea, vomiting, and headache. Continued exposure may cause increased light-headedness, staggering, unconsciousness, and even death. High vapor concentrations may also cause irritation of the eyes and respiratory tract. Exposure to MC may make the symptoms of angina worse. Skin exposure to the liquid MC may cause irritation. If the liquid MC is held in contact with the skin, it may cause skin burns. Splashes of the liquid into the eyes may cause irritation.

2. Long-term (chronic) exposure: The evidence for the carcinogenic potential of MC is primarily based upon chronic studies in which MC was administered to three species of laboratory rodents (rats, mice and hamsters). MC exposure produced lung and liver tumors in mice and mammary tumors in rats. No carcinogenic effects of MC were found in hamsters.

C. Reporting signs and symptoms: You should inform your employer if you develop any signs or symptoms and suspect that they are caused by exposure to MC.

#### D. Warning Properties:

1. Odor Threshold: Different authors have reported varying odor thresholds for MC. Kirk-Othmer and Sax both reported 25 to 50

ppm; Summer and May both reported 150 ppm; Spector reports 320 ppm. Patty, however, states that since one can become adapted to the odor, it cannot be considered that MC has an adequate warning property.

2. Eye Irritation Level: Grant reports that MC "presents no particular hazard to the eyes." Kirk-Othmer, however, reports that "MC vapor is seriously damaging to the eyes." Sax agrees with Kirk-Othmer's statement. The Documentation of TLVs states that irritation of the eyes has been observed in workers who had been exposed to concentrations up to 5000 ppm.

3. Evaluation of Warning Properties: Since there is a wide range of MC odor threshold (25-320 ppm), and human adaption to the odor, MC is considered as a material with poor warning properties.

### III. Emergency First Aid Procedures

In the event of emergency, institute first aid procedures and send for first aid or medical assistance.

A. Eye and Skin Exposures: If there is a potential that liquid MC can come in contact with eye or skin, face shields and skin protective equipment must be provided and used. If liquid MC comes in contact with the eye, get medical attention. Contact lenses should not be worn when working with this chemical.

B. Breathing: If a person breathes in large amounts of MC, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.

C. Rescue: Move the affected person from the hazardous exposure immediately. If the exposed person has been overcome, notify someone else and put into effect the established emergency rescue procedures. Understand the facility's emergency rescue procedures and know the locations of rescue equipment before the need arises. Do not become a casualty.

### IV. Respirators, Protective Clothing, and Eye Protection

A. Respirators: Good industrial hygiene practices recommend that engineering controls be used to reduce environmental concentrations to the permissible exposure level. However, there are some exceptions where respirators may be used to control exposure. Respirators may be used when engineering and work practice controls are not feasible, when such controls are in the process of being installed, or when these controls fail and need to be supplemented. Respirators may also be used for operations which require entry into tanks or closed vessels, and in emergency situations. If the use of respirators is necessary, the only respirators permitted are those that have been approved by the Mine Safety and Health Administration (MSHA) or the National Institute for Occupational Safety and Health (NIOSH). Supplied-air respirators are required because air-purifying respirators do not provide adequate respiratory protection against MC. In addition to respirator selections, a complete written respiratory protection program should be instituted which includes regular training.



maintenance, inspection, cleaning, and evaluation. If you can smell MC while wearing a respirator, proceed immediately to fresh air. If you experience difficulty in breathing while wearing a respirator, tell your employer.

**B. Protective Clothing:** Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent repeated or prolonged skin contact with liquid MC or contact with vessels containing liquid MC. Any clothing which becomes wet with liquid MC should be removed immediately and not reworn until the employer has ensured that the protective clothing is fit for reuse.

**C. Eye Protection:** Employees should be provided with and required to use splash-proof safety goggles where liquid MC may contact the eyes.

#### V. Housekeeping and Hygiene Facilities

For purposes of complying with 29 CFR 1910.141, the following items should be emphasized:

**A. The workplace should be kept clean, orderly, and in a sanitary condition.** The employer is required to institute a leak and spill detection program for operations involving liquid MC in order to detect sources of fugitive MC emissions.

**B. Emergency drench showers and eyewash facilities are recommended.** These should be maintained in a sanitary condition. Suitable cleansing agents should also be provided to assure the effective removal of MC from the skin.

**C. Because of the hazardous nature of MC,** contaminated protective clothing should be placed in a regulated area designated by the employer for removal of MC before the clothing is laundered or disposed of.

#### VI. Precautions for Safe Use, Handling and Storage

**A. Fire and Explosion Hazards:** MC has no flash point in conventional closed tester, but it forms flammable vapor-air mixtures at approximately 100 °C (212 °F), or higher. It has a lower explosion limit of 12%, and an upper explosion limit of 19% in air. It has an autoignition temperature of 556.1 °C (1033 °F), and a boiling point of 39.8 °C (104 °F). It is heavier than water with a specific gravity of 1.3. It is slightly soluble in water.

**B. Reactivity Hazards:** Conditions contributing to instability of MC are heat and moisture. Contact with strong oxidizers, caustics, and chemically active metals such as aluminum or magnesium powder, sodium and potassium may cause fires and explosions. Special precautions: Liquid MC will attack some forms of plastics, rubber, and coatings.

**C. Life Hazard:** Liquid MC is painful and irritating if splashed in the eyes or if confined on the skin by gloves, clothing, or shoes. Vapor in high concentrations may cause narcosis and death.

**D. Storage:** Protect against physical damage. Because of its corrosive properties, and its high vapor pressure, MC should be stored in plain, galvanized or lead lined, mild steel containers in a cool, dry, well ventilated area away from direct sunlight, heat source and acute fire hazards.

**E. Piping Material:** All piping and valves at the loading or unloading station should be of material that is resistant to MC and should be carefully inspected prior to connection to the transport vehicle and periodically during the operation.

**F. Usual Shipping Containers:** Glass bottles, 5- and 55-gallon steel drums, tank cars, and tank trucks.

**G. Electrical Equipment:** Electrical installations in Class I hazardous locations as defined in Article 500 of the National Electrical Code, should be installed according to Article 501 of the code; and electrical equipment should be suitable for use in atmospheres containing MC vapors. See Flammable and Combustible Liquids Code (NFPA No. 325M), Chemical Safety Data Sheet SD-86 (Manufacturing Chemists' Association, Inc.).

**H. Fire Fighting:** When involved in fire, MC emits high toxic and irritating fumes such as phosgene, hydrogen chloride and carbon monoxide. Wear breathing apparatus and use water spray to keep fire-exposed containers cool. Water spray may be used to flush spills away from exposures. Extinguishing media are dry chemical, carbon dioxide, foam. For purposes of compliance with 29 CFR 1910.307, locations classified as hazardous due to the presence of MC shall be Class I.

**I. Spills and Leaks:** Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until cleanup has been completed. If MC has spilled or leaked, the following steps should be taken:

1. Remove all ignition sources.
2. Ventilate area of spill or leak.
3. Collect for reclamation or absorb in vermiculite, dry sand, earth, or a similar material.

**J. Methods of Waste Disposal:** Small spills should be absorbed onto sand and taken to a safe area for atmospheric evaporation. Incineration is the preferred method for disposal of large quantities by mixing with a combustible solvent and spraying into an incinerator equipped with acid scrubbers to remove hydrogen chloride gases formed. Complete combustion will convert carbon monoxide to carbon dioxide. Care should be taken for the presence of phosgene.

**K. You must not keep food, beverage, or smoking materials, nor are you permitted to eat or smoke in regulated areas where MC concentrations are above the permissible exposure limits.**

**L. Portable heating units should not be used in confined areas where MC is used.**

**M. Ask your supervisor where MC is used in your work area and for any additional plant safety and health rules.**

#### VII. Medical Requirements

Your employer is required to offer you the opportunity to participate in a medical surveillance program if you are exposed to MC at concentrations exceeding the action level (12.5 ppm 8-hour TWA) for more than 30 days a year or at concentrations exceeding the PELs (25 ppm 8-hour TWA or 125 ppm 15-minute STEL) for more than 10 days a year. If you are exposed to MC at concentrations over either of the PELs, the medical surveillance will also include tests to ensure that you are able to wear the respirator that

you are assigned. Your employer must provide all medical examinations relating to your MC exposure at a reasonable time and place and at no cost to you.

#### VIII. Monitoring and Measurement Procedures

**A. Exposure above the Permissible Exposure Limit:**

**1. Eight-hour exposure evaluation:** Measurements taken for the purpose of determining employee exposure under this section are best taken with consecutive samples covering the full shift. Air samples must be taken in the employee's breathing zone.

**2. Monitoring techniques:** The sampling and analysis under this section may be performed by collection of the MC vapor on two charcoal adsorption tubes in series or other composition adsorption tubes, with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monitoring systems, portable direct reading instruments, or passive dosimeters as long as measurements taken using these methods accurately evaluate the concentration of MC in employees breathing zones.

OSHA methods 59 and 80 are examples of validated methods of sampling and analysis of MC. Copies of these methods are available from OSHA. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring must be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of MC at or above 25 ppm, and to plus or minus 35 percent for concentration at or below 25 ppm. In addition to OSHA methods 59 and 80, there are numerous other methods available for monitoring for MC in the workplace.

**B. Since many of the duties relating to employee exposure are dependent on the results of measurement procedures, employers must assure that the evaluation of employee exposure is performed by a technically qualified person.**

#### IX. Observation of Monitoring

Your employer is required to perform measurements that are representative of your exposure to MC and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear protective clothing and equipment.

#### X. Access to Information

**A. Each year, your employer is required to inform you of the information contained in this Appendix. In addition, your employer must instruct you in the proper work practices for using MC, emergency procedures, and the correct use of protective equipment.**



B. Your employer is required to determine whether you are being exposed to MC. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being over exposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits.

C. Your employer is required to keep records of your exposures and medical examinations. These records must be kept by the employer for at least thirty years (30).

D. Your employer is required to release your exposure and medical records to you or your representative upon your request.

#### XI. Common Operations and Controls

The following list includes some common operations in which exposure to MC may occur and control methods which may be effective in each case:

Operations	Controls
Use as solvent in paint and varnish removers; manufacture of aerosols; cold cleaning and ultrasonic cleaning; and as an extraction solvent for foods and furniture processing.	General dilution ventilation; local exhaust ventilation; personal protective equipment.
Use as solvent in vapor degreasing.	Process enclosure; local exhaust ventilation; chilling coils.
Use as a secondary refrigerant in air conditioning and scientific testing.	General dilution ventilation; local exhaust ventilation; personal protective equipment.

### Appendix B to § 1910.1052—Medical Surveillance for Methylene Chloride

#### I. Primary Route of Entry

Inhalation.

#### II. Toxicology

Methylene Chloride (MC) is primarily an inhalation hazard. The principle acute hazardous effects are the depressant action on the central nervous system and possible liver toxicity. The range of CNS effects are from a decreased eye/hand coordination and decreased performance in vigilance tasks to narcosis and even death of the individuals exposed at very high doses. Elevated liver enzymes and irritation to the respiratory passages and eyes have also been reported for both humans and experimental animals resulting from exposure to MC vapors. MC is metabolized to carbon monoxide and carbon dioxide via two separate pathways. Through the first pathway, MC is metabolized to carbon monoxide as an end-product via the P-450 mixed function oxidase pathway located in the microsomal fraction of the cell. This biotransformation of MC to carbon monoxide occurs through the process of microsomal oxidative dechlorination which takes place primarily in the liver. The amount of conversion to carbon monoxide is

significant as measured by the concentration of carboxyhemoglobin; up to 12% measured in the blood following occupational exposure of up to 610 ppm. Through the second pathway, MC is metabolized to carbon dioxide as an end product (with formaldehyde and formic acid as metabolic intermediates) via the glutathione dependent enzyme found in the cytosolic fraction of the liver cell. MC has been tested for carcinogenicity in several laboratory rodents. These rodent studies indicate that there is clear evidence that MC is carcinogenic to male and female mice and female rats. Based on three epidemiologic studies, OSHA preliminarily concludes that there is suggestive evidence of increased cancer risk in MC-related worker populations. The epidemiological evidence is consistent with the finding of excess cancer in the experimental animal studies. NIOSH regarded MC as a potential occupational carcinogen and the International Agency for Research Cancer (IARC) classified MC as an animal carcinogen. OSHA considered MC as a suspected human carcinogen.

#### III. Medical Signs and Symptoms of Acute Exposure

Skin exposure to liquid MC may cause irritation. If liquid MC comes in contact with the skin or eyes, it may cause skin irritations and burns. At very high concentrations in air, MC is an anesthetic and may cause breathing problems, leading to bronchitis and pulmonary edema, nausea, vomiting, light-headedness, numbness of the extremities, blood changes, unconsciousness and even death.

At lower concentrations in air, MC may cause irritation to the skin, eye, and respiratory tract and occasionally headache and nausea. Perhaps the greatest problem from exposure to low concentrations of MC is the CNS effects on coordination and alertness that may cause unsafe operations of machinery and equipment, leading to self-injury or accidents. Low levels and short duration exposures do not seem to produce permanent disability, but chronic exposures to MC have been demonstrated to produce liver toxicity in animals, and therefore, the evidence is suggestive for liver toxicity in humans after chronic exposure.

#### IV. Surveillance and Preventative Considerations

As discussed above, MC is classified as a suspect or potential human carcinogen. It is a central nervous system (CNS) depressant and a skin, eye and respiratory tract irritant. At extremely high concentrations, MC has caused liver damage in animals.

The principal toxic effect of MC is on the CNS, acting as a narcotic. The observation of the symptoms characteristic of CNS depression along with a physical examination would provide the best detection of early neurological disorders. Since exposure to MC also increases the carboxyhemoglobin level in the blood, ambient carbon monoxide levels would have an additive effect on that carboxyhemoglobin level. Based on such information, the medical surveillance should include a periodic carboxyhemoglobin test as an index of the presence of carbon monoxide in the blood.

Based on the animal evidence and three epidemiologic studies previously mentioned, OSHA preliminarily concludes that MC is a suspect human carcinogen. The proposed medical surveillance program is designed to observe exposed workers on a regular basis. While the proposed medical surveillance program cannot detect MC-induced cancer at a preneoplastic stage, OSHA anticipates that, as in the past, early detection and treatments of cancers leading to enhanced survival rates will continue to evolve.

#### A. Medical and Occupational History

The medical and occupational work history plays an important role in the initial evaluation of workers exposed to MC. It is therefore extremely important for the examining physician to evaluate the MC-exposed worker carefully and completely and to focus the examination on MC's potentially associated health hazards.

The medical evaluation should include a detailed work and medical history with special emphasis on neurological symptoms and mental status. A complete physical examination with special attention focusing on the lungs, liver, nervous system and breast with an evaluation of pre-existing skin disorders and history of cardiac disease should also be included.

The most important goal of the proposed medical history would be to elicit information from the worker regarding potential signs or symptoms associated with increased levels of carboxyhemoglobin due to the presence of carbon monoxide in the blood. Physicians should ensure that the smoking history of all MC exposed employees is known. Exposure to MC may cause a significant increase in carboxyhemoglobin level in all exposed persons. However, smokers as well as workers with anemia or heart disease and those concurrently exposed to carbon monoxide are at especially high risk of toxic effects because of an already reduced oxygen carrying capacity.

It is important for the physician to become familiar with the operating conditions in which exposure to MC is likely to occur. The physician also must become familiar with the signs and symptoms that may indicate that a worker is receiving otherwise unrecognized and exceptionally high exposure levels of MC.

#### B. Physical Examination

The complete physical examination, when coupled with the medical and occupational history, will assist the physician in detecting pre-existing conditions that might place the employee at increased risk, and will establish a baseline for future health monitoring. These examinations shall include, but shall not be limited to the following:

1. A comprehensive or interim medical and work history to include, but not limited to, occurrence of headache, dizziness, fatigue, pain in the limbs, and irritation of the skin and eyes.

2. A complete blood test that covers the following: white blood corpuscles, red blood corpuscles, hemoglobin, and hematocrit. In addition, clinical impressions of the nervous system and pulmonary function should be made, with additional tests conducted where



indicated or determined by the examining physician to be necessary.

3. An evaluation of the advisability of the workers using respirators, because the use of respirators places an additional burden on the cardiopulmonary system. It is necessary for the attending physician to evaluate the cardiopulmonary function of these workers, in order to inform the employer in a written medical opinion of the worker's ability or fitness to work in an area requiring the use of respiratory protective equipment. The presence of facial hair or scars that might interfere with the workers ability to wear certain types of respirators should also be noted during the examination and in the physician's medical opinion.

Because of the importance of lung function to workers required to wear respirators to protect themselves from MC exposure, these workers must receive an assessment of pulmonary function before they begin to wear a respirator and at least annually thereafter. The recommended pulmonary function tests include measurement of the employee's forced vital capacity (FVC), forced expiratory volume at one second (FEV1), as well as calculation of the ratios of FEV1 to FVC, and the ratios of measured FVC and measured FEV1 to expected respective values corrected for variation due to age, sex, race, and height. Pulmonary function evaluation must be conducted by a licensed physician experienced in pulmonary function tests.

4. It is also recommended that end of shift carboxyhemoglobin levels be determined periodically, and any level above 5% for non-smokers and above 8-10% for smokers should prompt an investigation of the worker and his workplace. This test is recommended because MC is metabolized to CO, which combines strongly with hemoglobin, resulting in a reduced capacity to transport oxygen in the body. This is of particular concern for cigarette smokers because they already have a diminished hemoglobin capacity due to the presence of CO in cigarette smoke.

#### C. Additional Examinations and Referrals

##### 1. Examination by a Specialist

When a worker examination reveals unexplained symptoms or signs (i.e. in the physical examination or in the laboratory tests), follow-up medical examinations would be necessary to assure that MC exposure is not adversely affecting the worker's health. When the examining physician finds it necessary, additional tests should be included to determine the nature of the medical problem and the underlying cause. Where relevant, the worker should be sent to a specialist for further testing and treatment as deemed necessary.

The proposal provides a mechanism whereby these additional investigations would be covered under the standard for occupational exposure to MC, and it also permits physicians to add appropriate or necessary tests to improve the diagnosis of disease should such tests become available in the future.

##### 2. Emergencies

The examination of workers exposed to MC in an emergency would be directed at the organ systems most likely to be affected. If the worker has received a severe acute

exposure, hospitalization may be required to assure proper medical intervention. It is not possible to precisely define "severe", but the physician's judgement should not merely rest on hospitalization. If the worker has suffered significant conjunctival, oral, or nasal irritation, respiratory distress, or discomfort, the physician should instigate appropriate follow-up procedures. These include attention to the eyes, lungs and the neurological system. The frequency of follow-up examinations should be determined by the attending physician. This testing would permit the early identification essential to proper medical management of such workers.

#### D. Employer Obligations

The employer would be required to provide the responsible physician and any specialists involved in a diagnosis with the following information: a copy of the MC standard including relevant appendices, a description of the affected employee's duties as they relate to his or her exposure to MC; an estimate of the employee's exposure including duration (e.g. 15hr/wk, three 8-hour shifts/wk, full time); a description of any personal protective equipment used by the employee, including respirators; and the results of any previous medical determinations for the affected employee related to MC exposure to the extent that this information is within the employer's control.

#### E. Physician's Obligations

The standard would require the employer to obtain a written statement from the physician. This statement would have to contain the physician's opinion, based on a written evaluation of test results and the physical examination, as to whether the employee has any medical condition placing him or her at increased risk of impaired health from exposure to MC or use of respirators, as appropriate. The physician would also have to state his or her opinion regarding any restrictions that should be placed on the employee's exposure to MC or upon the use of protective clothing or equipment such as respirators. If the employee wears a respirator as a result of his or her exposure to MC, the physician's opinion would have to also contain a statement regarding the suitability of the employee to wear the type of respirator assigned. Finally, the physician would have to inform the employer that the employee has been told the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion is not to contain any information on specific findings or diagnosis unrelated to employee's occupational exposures.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in assuring that their health is not being impaired by exposure to MC, and to assess the employee's ability to use any required protective equipment.

### Appendix C to § 1910.1052—Qualitative and Quantitative Fit Testing Procedures

#### A. Fit Test Protocols

The employer shall include the following provisions in the fit test procedures. These provisions apply to both qualitative fit testing (QLFT) and quantitative fit testing (QNFT).

1. The test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers. The selection shall include at least three sizes of elastomeric facepieces of the type of respirator that is to be tested, i.e., three sizes of half mask; or three sizes of full facepiece; or three sizes of quarter facepiece respirator, and units from at least two manufacturers.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

- (i) position of mask on the nose;
- (ii) room for eye protection;
- (iii) room to talk
- (iv) position of mask on face cheeks

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

- (i) chin properly placed;
- (ii) adequate strap tension, not overly tightened;
- (iii) fit across nose bridge;
- (iv) respirator of proper size to span distance from nose to chin;
- (v) tendency of respirator to slip;
- (vi) self-observation in mirror to evaluate fit; and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described below or ANSI Z88.2-1980. Before conducting the negative or positive pressure



test, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subjects fails to fit check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or long sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respiratory disease or pulmonary medicine to determine whether the test subject can wear a respirator while performing her or his duties.

11. The test subject shall be given the opportunity to wear the successfully fitted respirator for a period of two weeks. If at any time during this period the respirator becomes uncomfortable, the test subject shall be given the opportunity to select a different facepiece and to be retested.

12. The employer shall maintain a record of the fit test administered to an employee. The record shall contain at least the following information:

- (i) name of employee;
- (ii) type of respirator;
- (iii) brand, size of respirator;
- (iv) date of test;

(v) where QNFT is used: the fit factor, strip chart recording or other recording of the results of the test.

The record shall be maintained until the next fit test is administered.

13. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

14. Test Exercises. The test subject shall perform exercises, in the test environment, in the manner described below:

(i) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(ii) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(iii) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(iv) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(v) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

(vi) Grimace. The test subject shall grimace by smiling or frowning.

(vii) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(viii) Normal breathing. Same as exercise 1. Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

#### B. Qualitative Fit Test (QLFT) Protocols

##### 1. General

(i) The employer shall ensure that qualitative fit testing shall only be used for respirators to be worn in atmospheric concentrations of MC of 10 times the 8 hour TWA or less ( $10 \times 25 \text{ ppm} = 250 \text{ ppm}$ ).

(ii) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(iii) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(iv) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

##### 2. Isoamyl Acetate Protocol

###### (i) Odor Threshold Screening

The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(a) Three 1 liter glass jars with metal lids are required.

(b) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(c) The isoamyl acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(d) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated but shall not be connected to the same recirculating ventilation system.

(e) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(f) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(g) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can

be periodically peeled, dried off and switched to maintain the integrity of the test.

(h) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

(i) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(j) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(k) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

###### (ii) Isoamyl Acetate Fit Test

(a) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(b) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

(c) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(d) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(e) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(f) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the head exercises; or to demonstrate some of the exercises.

(g) If at any time during the test, the subject detects the banana like odor of IAA, the test has failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.



(h) If the test has failed, the subject shall return to the selection room and remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber and again begin the procedure described in (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(i) When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(j) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test. To keep the test area from becoming contaminated, the used towels shall be kept in a self sealing bag so there is no significant IAA concentration build-up in the test chamber during subsequent tests.

### 3. Saccharin Solution Aerosol Protocol

The saccharin solution aerosol QLFT protocol is the only currently available, validated test protocol for use with particulate disposable dust respirators not equipped with high-efficiency filters. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

#### (i) Taste threshold screening

The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(a) Threshold screening as well as fit testing subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(b) The test enclosure shall have a 3/4-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(c) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her wide open mouth with tongue extended.

(d) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(e) The *threshold check solution* consists of 0.83 grams of sodium saccharin USP in 1 cc of warm water. It can be prepared by putting 1 cc of the fit test solution (see (b)(5) below) in 100 cc of distilled water.

(f) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(g) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(h) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(i) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(j) The test conductor will take note of the number of squeezes required to solicit a taste response.

(k) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(l) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(m) Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

(n) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

#### (ii) Saccharin Solution Aerosol Fit Test Procedure

(a) The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

(b) The fit test uses the same enclosure described in (a) above.

(c) The test subject shall don the enclosure while wearing the respirator selected in section (a) above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(d) A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(e) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

(f) As before, the test subject shall breathe through the open mouth with tongue extended.

(g) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(h) After generating the aerosol the test subject shall be instructed to perform the exercises in section I.A.14 above.

(i) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(j) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(k) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

### 4. Irritant Fume Protocol

(i) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(ii) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its characteristic odor.

(iii) Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute.

(iv) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(v) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(vi) The exercises identified in section I.A.14 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(vii) Each test subject passing the smoke test without evidence of a response shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(viii) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

### C. Quantitative Fit Test (QNFT) Protocol

#### 1. General

(i) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(ii) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(iii) The employer shall assure that QNFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

#### 2. Definitions

(i) Quantitative fit test. The test is performed in a test chamber. The normal air-purifying element of the respirator is replaced by a high-efficiency particulate air (HEPA) filter in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(ii) Challenge agent means the aerosol, gas or vapor introduced into a test chamber so that its concentration inside and outside the respirator may be measured.

(iii) Test subject means the person wearing the respirator for quantitative fit testing.

(iv) Normal standing position means standing erect and straight with arms down along the sides and looking straight ahead.

(v) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.



(vi) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

### 3. Apparatus

(i) Instrumentation. Aerosol generation, dilution, and measurement systems using corn oil or sodium chloride as test aerosols shall be used for quantitative fit testing.

(ii) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(iii) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter supplied by the same manufacturer.

(iv) The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(v) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process.

(vi) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed); a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator.

(vii) The test chamber and test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(viii) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent inside the test chamber constant to within a 10 percent variation for the duration of the test.

(ix) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event inside the test chamber and its being recorded.

(x) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(xi) The exhaust flow from the test

chamber shall pass through a high-efficiency filter before release.

(xii) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(xiii) The limitations of instrument detection shall be taken into account when determining the fit factor.

(xiv) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

### 4. Procedural Requirements

(i) When performing the initial positive or negative pressure test the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these tests.

(ii) An abbreviated screening isoamyl acetate test or irritant fume test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. When performing a screening isoamyl acetate test, combination high-efficiency organic vapor cartridges/canisters shall be used.

(iii) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(iv) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(v) A stable challenge concentration shall be obtained prior to the actual start of testing.

(vi) Respirator restraining straps shall not be overtightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable comfortable fit typical of normal use.

(vii) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested. If two of the three required tests are terminated, the fit shall be deemed inadequate.

(viii) In order to successfully complete a QNFT, three successful fit tests are required. The results of each of the three independent fit tests must exceed the minimum fit factor needed for the class of respirator (e.g., quarter facepiece respirator, half mask respirator, full facepiece respirator).

(ix) Calculation of fit factors.

(a) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration inside the respirator.

(b) The average test chamber concentration is the arithmetic average of the test chamber concentration at the beginning and of the end of the test.

(c) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(1) Average peak concentration.

(2) Maximum peak concentration.

(3) Integration by calculation of the area under the individual peak for each exercise.

This includes computerized integration.

(x) Interpretation of test results. The fit factor established by the quantitative fit testing shall be the lowest of the three fit factor values calculated from the three required fit tests.

(xi) The test subject shall not be permitted to wear a half mask, quarter facepiece, or full facepiece respirator unless a minimum fit factor equivalent to at least 10 times the hazardous exposure level is obtained.

(xii) Filters used for quantitative fit testing shall be replaced at least weekly, or whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily (when used) or sooner if there is any indication of breakthrough by a test agent.

### Facepiece Seal Fit Checks—Recommended Procedures

A. *Positive pressure fit check.* Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators, this method of leak testing requires the wearer to first remove the exhalation valve and then carefully replacing it after the test.

B. *Negative pressure fit check.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

### Shipyard Employment

Part 1915 of title 29 of the Code of Federal Regulations is proposed to be amended as follows:

### PART 1915—[AMENDED]

6. The authority citation for part 1915 is proposed to be revised as follows:

Authority: Sec. 41, Longshore and Harbor Workers Compensation Act (33 U.S.C. 941); secs. 4, 6, and 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655 and 657); Secretary of Labor's Order No. 1-90 (55 FR 9033); and 29 CFR part 1911.

### Subpart Z—[Added]

7. 29 CFR part 1915 is proposed to be amended by adding a new subpart Z toxic and hazardous substances, consisting of § 1915.1102 methylene chloride. The text of § 1915.1102 would be identical to the text of § 1910.1052.

### Construction Industry

Part 1926 of title 29 of the Code of Federal Regulations is proposed to be amended as follows:



**PART 1926—[AMENDED]**

8. The authority citation for part 1926 is proposed to be revised as follows:

Authority: Sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 1-90 (55 FR 9033); and 29 CFR part 1911.

9. 29 CFR part 1926 is proposed to be amended by adding a new § 1926.61 methylene chloride, to subpart D. The text of § 1926.61 would be identical to the text of § 1910.1052.

[FR Doc. 91-26180 Filed 11-6-91; 8:45 am]

BILLING CODE 4510-26-M







# Environmental Protection

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Thursday  
November 7, 1991

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## Part III

### Environmental Protection Agency

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40 CFR Parts 704 and 799

Glycidol and Its Derivatives Category;  
Proposed Test Rule With Reporting and  
Recordkeeping Requirements



# ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Parts 704 and 799

[OPTS-42051A; FRL 3736-2]

RIN: 2070-AB07

### Glycidol and Its Derivatives Category; Proposed Test Rule With Reporting and Recordkeeping Requirements

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA, under section 4 of the Toxic Substances Control Act (TSCA), is proposing that manufacturers and processors of chemical substances listed on the public or confidential portions of the TSCA section 8(b) Chemical Substance Inventory that belong to the "Category of glycidol and its derivatives" (hereinafter referred to as "glycidyls"), be required to perform health effects testing. EPA is also proposing under TSCA section 8(a) that manufacturers and importers of glycidyls be required to report to EPA the volume of manufacture and importation of the substances in accordance with 40 CFR part 704 to allow EPA to determine when certain tests are to be performed.

**DATES:** Submit written comments on or before February 5, 1991. If persons request an opportunity to submit oral comment by February 5, 1991, EPA will hold a public meeting on this rule in Washington, DC.

**ADDRESSES:** Submit written comments, identified by the document control number (OPTS-42051A), in triplicate to: TSCA Public Docket Office (TS-793), rm. NE-G004, Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to noon, and 1 p.m. to 4 p.m., Monday through Friday except legal holidays.

For further information on arranging to speak at the public meeting, see Unit IX. of this preamble, and contact: Mary Louise Hewlett, Chemical Testing Branch (TS-778), rm. NE-100, Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW.,

**FOR FURTHER INFORMATION CONTACT:** David Kling, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

**SUPPLEMENTARY INFORMATION:** EPA is issuing a proposed test rule under section 4(a) of TSCA requiring health effects testing of chemical substances falling within the chemical category of glycidyls. For purposes of this proposed rule, EPA has defined "glycidyls" as glycidol itself and any of its esters or ethers which are currently listed on, or are subsequently listed on, the public or confidential portions of the TSCA section 8(b) Inventory of Chemical Substances. Under TSCA section 8(a), EPA is also proposing annual reporting by manufacturers (including importers) of production and/or importation volumes for these substances to determine when certain testing will begin. The glycidyls are a complicated category of chemicals that present many unique factors to consider in developing an appropriate test rule. Although EPA is proposing this test rule, EPA expects to seriously consider all alternative approaches and may promulgate a test rule that is substantially different from today's proposal. Because of the length and complexity of this proposed rule, the following Table of Contents is presented as an aid to the reader.

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## I. Introduction

## A. Overview

1. *Testing required by the rule.* Under this rule, EPA is proposing a testing scheme based on subcategories of related substances as well as individual substances. EPA recognizes that not all glycidyls listed on the public or confidential portions of the TSCA Inventory of Chemical Substances are in current production, and that some members of the category may be used as substitutes for others. Therefore, to mitigate testing costs and to prevent manufacturers and processors from switching production from one substance to another to avoid testing requirements, EPA is proposing a cost-sharing testing mechanism using subcategories of substances. EPA would select one substance within a subcategory for testing which would be paid for by manufacturers and processors of all the substances within the subcategory. The mutagenicity and oncogenicity data from the representative member would then be used for risk assessment for all members of the subcategory.

For subcategories of substances produced in aggregate quantities of at least 1 million pounds per year and less than 10 million pounds per year, EPA proposes that one member of the subcategory be tested for: Subchronic toxicity, developmental toxicity screening, mutagenicity screening, and subchronic neurotoxicity.

For subcategories of substances produced in aggregate quantities of 10 million pounds or greater per year, EPA proposes that one member of the subcategory be tested for: Subchronic toxicity, developmental toxicity, reproductive toxicity, neurotoxicity (subchronic and acute), mutagenicity and oncogenicity.

Any subcategory which reached the aggregate production volume trigger of 1 million pounds at one given time and, subsequently, reached the 10 million pound trigger at another time, would be subject to both testing batteries, each one conducted when the respective production volume trigger was met. Under section 8(a) of TSCA, EPA shall, by rule, require the manufacturers and processors of a chemical substance to maintain specific records and submit reports to EPA. To determine when certain testing is triggered, EPA is proposing under section 8(a) of TSCA to

require annual reporting by manufacturers (including importers) of production and importation volumes for all substances meeting the definition of this chemical category.

In addition to testing requirements based on the production volume of a subcategory, if EPA has a concern for subchronic, developmental, reproductive, or neurotoxic effects based on preliminary data on a particular substance, EPA would require immediate testing of that substance only by the manufacturers and processors of that substance. If EPA has a concern for mutagenicity based on preliminary data on any substance within a subcategory, EPA would require immediate mutagenicity testing of a representative member of that subcategory by the manufacturers and processors of all the substances within that subcategory. The entry assay within the tiered mutagenicity testing schemes for gene mutation and chromosomal aberration would depend on the last test for which data are available and adequate for any member of the subcategory. If EPA has a concern for oncogenicity based on preliminary data on any substance within a subcategory, EPA would require immediate testing of a representative member of the substances within the subcategory by the manufacturers and processors of all the substances in the subcategory only if the aggregate annual subcategory production volume is also in excess of 10 million pounds per year.

2. *Other considerations.* This rule adopts an innovative approach for rules under section 4 of TSCA in that EPA is making findings for an entire category of substances. EPA is proposing to make these "category-wide" findings under both section 4(a)(1)(A) and section 4(a)(1)(B) of TSCA. (See Unit IV. of this preamble) EPA is basing the TSCA section 4(a)(1)(A) findings on available data and application of structure-activity relationships (SAR).

As a category rule, the proposed rule would apply to both existing and new substances. A glycidyl derivative not on the TSCA section 8(b) inventory would go through the premanufacture notification (PMN) process under TSCA section 5(a) and be entered on the inventory after beginning production. TSCA section 5 requires that, when a category of substances is subject to a TSCA section 4 test rule, any PMN submission on a member of the category must include the required test data. However, EPA does not intend to make compliance with these data requirements a condition for submitting a PMN, but rather will defer compliance until after the substance is reported to

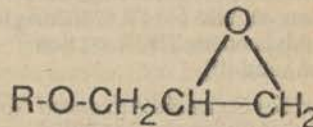
the TSCA Inventory. (See Units III.B., III.G., and V.D. of this preamble)

Any glycidyls category member on the TSCA inventory that is in production at the time of final test rule promulgation would be a candidate for immediate testing, but, as described below, might escape designation as a test substance. A TSCA section 8(a) annual reporting rule, proposed together with this test rule, would provide the means for EPA to monitor substance and subcategory production. (See Unit III.G. of this preamble)

Because new data may appear between the date the final rule is issued and the date testing is triggered, EPA proposes to let test sponsors submit such new data before it notifies sponsors to begin testing. (See Unit V.A. of this preamble)

## B. ITC Recommendation

The Interagency Testing Committee (ITC) designated the category of "glycidol and its derivatives" for health effects testing. The reasons for this designation are discussed in the Federal Register of October 30, 1978 (43 FR 50630). This chemical category was defined by the ITC as all substances of the general formula:



where R is a hydrogen atom or any alkyl, aryl, or acyl group. R is unrestricted as to the number and type of substituents it may carry.

## C. Test Rule Development Under TSCA

Under section 4(a) of TSCA, EPA shall, by rule, require testing of a chemical substance or mixture (substance) to develop appropriate test data if the Administrator makes certain findings as described in TSCA under section 4(a)(1)(A) or (B). Detailed discussions of the statutory TSCA section 4 findings are provided in EPA's first and second proposed test rules which were published in the Federal Register of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300).

Under TSCA section 26, EPA has authority to take any action authorized or required to be taken with respect to a chemical substance or mixture that may be taken with respect to a category of substances or mixtures. TSCA section 26(c)(2) defines "category of chemical substances" to mean:



a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

Thus, the term "category of chemical substances" is quite broad.

In evaluating the testing needs for the glycidyls, EPA considered all available relevant information, including the following: Information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of glycidyls under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR part 712); health and safety studies submitted under the TSCA section 8(d) Health and Safety Study Reporting Rule (40 CFR part 716) for glycidyls; and published and unpublished data available to EPA. EPA also considered public comments on the advance notice of proposed rulemaking for testing of glycidyls under section 4(a) of TSCA (hereinafter "ANPR") that was published in the *Federal Register* of December 30, 1983 (48 FR 57562) for the glycidyls under TSCA section 4(a)(1)(A) and (B).

#### *D. Activities Since the Advanced Notice of Proposed Rulemaking (ANPR)*

Since publication of the ANPR on December 30, 1983, EPA has evaluated public comments and incorporated EPA's responses to these comments in a separate support document (Ref. 1), entitled "Support Document for Glycidol and its Derivatives: Responses to Public Comments on the Advance Notice of Proposed Rulemaking (December, 1989)".

In addition, EPA compiled a technical support document for glycidol and its derivatives (Ref. 2). This document includes data on the identity and chemical/physical properties of the substances contained in this chemical category, as well as information on the production, uses, chemical fate, human exposure, and health effects for these substances. Data obtained in comments on the ANPR, as a result of TSCA section 8(d) or (e) submissions, or as a result of publication in the open scientific literature subsequent to the issuance of the ANPR, were included in this document. Subsequently, EPA summarized the information in the technical support document (Ref. 2), as well as more recent information from

other sources, in an additional support document for glycidyls (Ref. 3) outlining the data supporting EPA's findings under section 4(a)(1)(A) of TSCA for certain of the substances contained in the category.

A meeting was held on May 17, 1984, between representatives from the Epoxy Resins Program Panel of the Chemical Manufacturers Association (CMA) and EPA personnel concerning this chemical category. Meetings were also held on January 25, 1989, and May 17, 1989, between EPA and representatives of various working units of the Society of the Plastics Industry, Inc. (SPI). An Epoxides Workshop was held on April 25, 1990, at which EPA personnel and representatives of SPI were scheduled to discuss, among other topics, the glycidyls testing category as it relates to the broader issues posed by epoxides in general. Although EPA subsequently withdrew the glycidyls testing presentation, a copy of the overhead projection slides, which were supplied in advance to SPI, has been placed in the record for this rulemaking. Summaries of the meetings held, as well as copies of all support documents, have been placed in the record for this rulemaking.

## **II. Review of Available Data**

### *A. Profile*

The chemical structures and physical and chemical properties of the 66 substances listed on the public portion of the TSCA section 8(b) Chemical Substance Inventory, which fall within the glycidyls definition, are presented in the technical support document (Ref. 2). As described in Unit III.C.1. of this preamble, for the purposes of this test rule, these 66 substances have been divided to yield glycidol itself and 21 subcategories of its derivatives, using SAR principles (considering only molecular structure and observed health effects). The chemical substances for which reports have been received pursuant to the Inventory Update Rule (40 CFR part 710, subpart B), or for which EPA has obtained other data which indicate recent production and/or importation, are identified by footnote in the subcategorization scheme presented in Unit III.C.1. of this preamble.

### *B. Production*

Glycidol may be produced by reacting perbenzoic acid with allyl alcohol or by reacting glycerol-1-monochlorohydrin with alcoholic potassium hydroxide or metallic sodium in ether (Ref. 4). The glycidyl derivatives are produced by reacting epichlorohydrin with a compound having one or more active

hydrogen atoms, followed by dehydrohalogenation with a suitable base (Ref. 5). On the basis of information obtained from the Inventory Update Rule (40 CFR part 710, subpart B) or from other sources, EPA estimates that recent annual production volumes (mostly data for 1985) for the monomeric substances contained in this chemical category have totalled as much as 25 million pounds (Ref. 6). In addition, EPA estimates that the total annual production volume for these monomeric substances has reached approximately 343 million pounds, including the volumes of monomeric substances present in significant amounts as byproducts in epoxy resins (Ref. 7). These monomeric substances arise as unavoidable byproducts during the manufacture of epoxy resins.

### *C. Uses*

Glycidyls' uses are listed in the technical support document (Ref. 2). Glycidol is primarily used as a stabilizer during the production of certain vinyl polymers. Glycidol ethers and esters are mainly used as reactive diluents in the production of epoxy resins, which are then reacted with curing agents to yield high-performance thermosetting plastics, used in a large variety of situations requiring strong adhesives or coatings.

### *D. Exposure*

Glycidol and its esters and ethers are produced within "closed systems" (Refs. 8 and 9); however, EPA believes that some worker exposure may occur during these production processes, due to intermittent higher-level exposures during maintenance operations, or resulting from spills or leaks from the "closed systems." Similar worker exposure to glycidol may occur during its primary use as a stabilizer in the manufacture of vinyl polymers in "closed systems."

Substantial numbers of workers are or may be exposed by the dermal and inhalation routes to glycidyl derivatives during the processing of glycidyl ethers and esters for various uses, particularly since these processes are generally conducted in open systems (Ref. 8). The National Institute for Occupational Safety and Health (NIOSH) has estimated the numbers of workers potentially exposed to glycidol and some of its derivatives, and these estimates are presented in an exposure support document for this proposed rule (Ref. 6). NIOSH has estimated that 36,697 workers in the United States are potentially exposed to glycidol, that 52,838 workers may be exposed to glycidyl ethers, and that 42,469 workers



may be exposed to glycidyl esters, based on the two esters for which estimates were made (glycidyl methacrylate and glycidyl oleate). Earlier, NIOSH estimated that approximately 118,000 workers in the United States are potentially exposed to glycidyl ethers (Ref. 10). New interest in the use of pure enantiomers of glycidol and substituted glycidyls and their esters for the preparation of optically pure drugs and pheromones (Ref. 11) may lead to an increase in the number of workers exposed to members of this chemical category during production and processing of glycidol and its derivatives.

In comments on the ANPR, a few manufacturers provided data on the number of workers they believed to be exposed during their production operations. In addition, several industrial hygiene surveys, submitted by industry pursuant to TSCA section 8(d) or (e), or published in the open scientific literature, were evaluated by EPA (Ref. 2). EPA has carefully considered this information, but has concluded that the NIOSH estimates provide a more accurate prediction of potential worker exposures for the following reasons: For substances having more than one manufacturer in the United States, not all manufacturers supplied worker-exposure data. Even for substances having only one manufacturer in the United States, the worker-exposure data provided for production did not include the exposure of workers during processing operations (not considered in the manufacturers' surveys) using the substance produced by the reporting manufacturer or the same substance imported from other sources, and data were not submitted for all of the substances in this chemical category which EPA believes to be currently produced domestically or imported.

Occupational exposure to certain glycidyls has occurred for some time. Standards recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) and NIOSH for limiting atmospheric workplace contamination by glycidyls are listed in an exposure support document (Ref. 8). The current standards for glycidyls issued by the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) are listed at 29 CFR 1910.1000. These standards are intended to protect workers from skin irritation and sensitization, as well as other systemic effects, but are based only on reported dermal effects in humans and the results of a limited number of laboratory animal

studies for a limited number of health effects.

With respect to commercial and consumer exposure to these substances, EPA does not expect substantial exposure to glycidol itself, but anticipates substantial dermal and/or inhalation exposure to glycidyl ethers and esters due primarily to the commercial and consumer uses of epoxy resin products, especially the two-part resin systems. Based on the comments on the ANPR by Marubeni America Corporation, glycidyl methacrylate (CAS No. 106-91-2) could occur as a residual byproduct in latex and acrylic paints because of the way these products are produced. These paints have widespread consumer use, leading to potential consumer exposure to glycidyl methacrylate. Although the company claims that no residual free monomeric glycidyl methacrylate remains in these paints prior to consumer use, no data were supplied to support this claim. Thus, consumers may be exposed to this substance by use of acrylic and latex paints. Other members of this chemical category also have solvent and other uses that may lead to consumer exposure (Ref. 2). Recent estimates suggest that up to 3 million people in the United States may be exposed dermally or by inhalation to glycidyl ethers through the consumer and commercial use of epoxy resins (Ref. 9). In terms of milligrams (mg) of total glycidyl ethers per year per individual, consumers are estimated to be exposed to 7.1 to 71 mg/yr per individual by inhalation and 104 to 1,040 mg/yr per individual by dermal contact, while individuals using epoxy resins commercially are estimated to be exposed to 140,000 to 1,400,000 mg/yr per individual by inhalation and 150,000 to 1,500,000 mg/yr per individual by dermal contact.

Because bisphenol A diglycidyl ether (CAS No. 1675-54-3), bisphenol F diglycidyl ether (CAS No. 54208-63-8), and various dimers and trimers of these substances have been detected in British drinking waters derived from lowland river water and groundwater in water systems whose mains had been relined with epoxy resin (Ref. 12), it is possible that large numbers of people in the United States may be exposed via drinking water to parts-per-billion (ppb) levels of these or other derivatives of glycidol under similar conditions. EPA's Office of Drinking Water has confirmed that several materials which are accepted for use in drinking water systems in the United States as protective paints and coatings, or as concrete admixtures for increasing durability, do contain glycidyls that may

leach into drinking water. However, no monitoring data are available on the presence or absence of these substances in United States drinking water.

#### *E. Environmental Release*

Little information is available regarding the environmental releases of glycidyls (Ref. 2). Few environmental releases are expected during the production of glycidol or its esters and ethers, since production occurs in essentially "closed systems" (Refs. 8 and 9). However, during processing operations and use, glycidyls will be released by volatilization and in process waste water. Some of these substances may also be released unchanged in the effluent from industrial waste water treatment plants, although no monitoring data are available. Leaching of glycidyls from cured epoxy resins is expected to be minimal (Ref. 2), although as discussed in Unit II.D. of this preamble, this process may lead to limited exposure levels in drinking water.

#### *F. Health Effects*

Because of the number of substances in this chemical category and the total number of health effects studies evaluated for these substances, it is infeasible to present EPA's evaluation of each study in the preamble to this proposed rule. For that reason, a support document (Ref. 3) discussing only health effects studies EPA believes to be pertinent to making findings under section 4(a)(1)(A) of TSCA has been prepared and placed in the rulemaking record. EPA's evaluation of studies not discussed in this support document (Ref. 3) may be found in the technical support document (Ref. 2). A summary of data that support findings for this rule is in Table 1 of Unit IV. of this preamble.

Many of the studies submitted to EPA pursuant to section 8(d) of TSCA, as well as some studies published in the open scientific literature, were deficient because the test substance was not adequately described. For example, the purity of the test substance, the identity of major impurities present, the degree of polymerization, and the average molecular weight were not given. In such cases, EPA did not evaluate the studies in depth. Furthermore, EPA did not evaluate studies submitted for polymeric resins, since EPA believes that any adverse health effects shown by these high-molecular-weight substances will be due primarily to residual low-molecular-weight reactants. Because the low-molecular-weight members of this chemical category are expected to be the most toxic, EPA is proposing that the testing



for the glycidyls chemical category be performed with monomeric substances.

Evaluations of mutagenicity and oncogenicity studies appear in the support document (Ref. 3) by subcategories, as defined in Unit III.C.1. of this preamble. Other health effects studies are discussed in the support document (Ref. 3) on a chemical-specific basis. This approach is used because, in addition to proposing testing of substances triggered by production volume, EPA proposes to require mutagenicity and oncogenicity testing of one representative member of a subcategory if data for a member of a subcategory indicate a concern for these effects. (For oncogenicity testing, annual aggregate subcategory production volume must also exceed 10 million pounds.) For other health effects testing, EPA proposes to require testing of individual substances when preliminary data on a specific substance indicates a concern for a particular health effect.

### III. Regulatory Approach Used in this Test Rule

To ensure that adequate data are developed for this category, while avoiding overly burdensome testing, EPA has taken the following approach in developing the proposed test rule for this large chemical category.

#### A. Substances to Which the Rule Would Apply

There are 66 substances listed on the public portion of the TSCA Chemical Substance Inventory, and there may be some substances listed on the confidential portion of the Inventory, which fall within the glycidyls definition. In this rule, EPA is proposing findings for the category of glycidyls, including glycidol and all 21 subcategories of its derivatives. Also, EPA proposes to include any substance meeting the category definition that is entered into the public or confidential portion of the TSCA Inventory of Chemical Substances after completion of the TSCA premanufacture review process under section 5 of TSCA. EPA has constructed this proposed test rule such that it would require immediate

testing only for glycidyls for which EPA has received reports pursuant to the Inventory Update Rule (40 CFR 710.23) or for which EPA has obtained other data indicating current production. Using these criteria, EPA believes that only 32 of the 66 chemical substances in this chemical category and listed on the public portion of the TSCA Chemical Substances Inventory are in current production. These 32 substances have been identified in the subcategorization scheme proposed for the chemical category in Unit III.C.1. of this preamble.

#### B. Types of Testing Required for Substances Triggered by Production Volume

For the purposes of this rule only, for subcategories having aggregate annual production volumes equal to or greater than 1 million pounds but less than 10 million pounds, EPA proposes the following tests for representative subcategory members: Oral subchronic (90-day) toxicity in the rat; the Chernoff screening test for developmental toxicity in the rat; limited testing for mutagenicity, including the Ames gene mutation test, the mouse lymphoma L5178Y TK  $\pm$  gene mutation test, the *in vitro* cytogenetics test using Chinese hamster ovary cells, and the *in vivo* cytogenetics test in the mouse; and oral subchronic (90-day) neurotoxicity testing in the rat, including the functional observation battery, the motor activity test, and neuropathology. EPA is proposing that a representative member from each of the following subcategories, which EPA believes currently meet the production criterion, be tested in this manner: I-A; I-C; II-A; III-A; IV-A; V-B; VII-A; and VII-B (see Unit III.C.1. of this preamble for subcategory definitions). Should the results from these proposed tests so indicate, EPA may propose further testing for substances contained in these subcategories.

For the purposes of this rule only, as soon as a subcategory reaches an aggregate annual production volume of 10 million pounds or more (even if testing described for subcategories having annual aggregate production

volumes equal to or greater than 1 million but less than 10 million pounds has been previously conducted), EPA is proposing the following tests for a representative subcategory member: Oral oncogenicity bioassays in rats and mice; oral subchronic (90-day) toxicity studies in rats and mice; oral developmental toxicity tests in rats and mice; oral two-generation reproductive toxicity testing in rats; oral neurotoxicity testing in rats, including acute and subchronic (90-day) functional observation batteries, acute and subchronic (90-day) motor activity tests, and subchronic (90-day) neuropathology; and complete test batteries for gene mutation and chromosomal aberration beginning with the first assay in each test battery for which data are inadequate. EPA is proposing that a representative member of Subcategory VI-A, the only subcategory which EPA believes currently has an aggregate annual production volume of greater than 10 million pounds, be tested in this manner.

#### C. Use of Structure-Activity Relationships (SAR) and Subcategories

In this proposed rule, EPA has used SAR: (1) To divide the glycidyls category into subcategories for which it is appropriate to require, for oncogenicity and mutagenicity, testing of one substance representing its subcategory as sufficient testing for the subcategory; and (2) to select the representative test substance.

EPA has used SAR in the following ways:

1. *Defining subcategories.* EPA used SAR principles to divide the 66 category members listed on the public portion of the TSCA Chemical Substance Inventory into glycidol and 21 subcategories of its derivatives. EPA's proposed subcategorization scheme is a refinement of the one presented in the ANPR. The SAR bases for the scheme appear in the document, "Subcategorization Scheme for Glycidol Ethers and Esters" (Ref. 13), placed in the record for this rulemaking. The scheme itself is as follows:

#### SUBCATEGORIZATION SCHEME FOR GLYCIDOL AND ITS DERIVATIVES

Sub-category	Description of R or chemical name	CAS No.
None	Glycidol (R = H atom)	1556-52-5
I	R = alkyl group with <11 carbons:	
I-A	Unsubstituted saturated alkyl:	
	Methyl glycidyl ether	930-37-0
	n-Butyl glycidyl ether	12426-08-6
	Ethyl glycidyl ether	4016-11-9
	Isopropyl glycidyl ether	4016-14-2



## SUBCATEGORIZATION SCHEME FOR GLYCIDOL AND ITS DERIVATIVES—Continued

Sub-category	Description of R or chemical name	CAS No.
I-B	<i>tert</i> -Butyl glycidyl ether.....	<sup>1</sup> 7665-72-7
	1,3-Dimethylbutyl glycidyl ether.....	68134-06-5
	6-Methylheptyl glycidyl ether.....	68134-07-6
	Alkyl (C <sub>8</sub> -C <sub>10</sub> ) glycidyl ether.....	<sup>1</sup> 68609-86-1
	Alkyl (C <sub>8</sub> -C <sub>12</sub> ) glycidyl ether.....	68987-80-4
	Halogenated saturated alkyl containing no additional epoxide substituent:.....	
	1,2-Dibromopropyl glycidyl ether.....	35243-89-1
	Unsaturated alkyl containing no halogen or additional epoxide substituents:.....	
	Allyl glycidyl ether.....	<sup>1</sup> 106-92-3
	2-Ethylhexyl group:.....	
I-D	2-Ethylhexyl glycidyl ether.....	<sup>1</sup> 2461-15-6
II	<b>R = alkyl group with <math>\geq 11</math> carbons:</b>	
II-A	Unsubstituted saturated alkyl:.....	
	Lauryl glycidyl ether.....	<sup>1</sup> 2461-18-9
	Hexadecyl glycidyl ether.....	15965-99-8
	<i>n</i> -Octadecyl glycidyl ether.....	16245-97-9
	Tetradecyl glycidyl ether.....	38954-75-5
	Alkyl (C <sub>10</sub> -C <sub>18</sub> ) glycidyl ether.....	<sup>1</sup> 68081-84-5
II-B	Alkyl (C <sub>12</sub> -C <sub>14</sub> ) glycidyl ether.....	<sup>1</sup> 68609-97-2
	Unsaturated alkyl containing no halogen or additional epoxide substituents:.....	
	Oleyl glycidyl ether.....	60501-41-9
III	<b>R = silicon-containing alkyl group:</b>	
III-A	Saturated alkyl group with no halogen or additional epoxide substituents:.....	
	3-(Trimethoxysilyl)propyl glycidyl ether.....	<sup>1</sup> 2530-83-8
	3-(Methyl diethoxysilyl)propyl glycidyl ether.....	2897-60-1
	3-[Bis(trimethylsiloxy)methyl]propyl glycidyl ether.....	7422-52-3
	3-(Dimethylethoxysilyl)propyl glycidyl ether.....	17963-04-1
III-B	Halogenated, saturated alkyl group with no additional epoxide substituent:.....	
	(3-Chloropropyl)dimethoxy-[3-(oxiranylmethoxy)propyl] silane.....	71808-64-5
III-C	Non-halogenated, saturated alkyl group with an additional epoxide substituent:.....	
	1,3-Bis[3-(2,3-epoxypropoxy)propyl]tetramethyldisiloxane.....	126-80-7
	1,1,1,3,5,7,7-Octamethyl-3,5-bis(6,7-epoxy-4-oxaheptyl)tetrasiloxane.....	69155-42-6
IV	<b>R = aryl group:</b>	
IV-A	Aryl group with no halogen, or additional epoxide substituents:.....	
	Phenyl glycidyl ether.....	<sup>1</sup> 122-60-1
	<i>o</i> -Cresyl glycidyl ether.....	<sup>1</sup> 2210-79-9
	<i>p</i> - <i>tert</i> -Butylphenyl glycidyl ether.....	<sup>1</sup> 3101-60-8
	<i>p</i> -Nonylphenyl glycidyl ether.....	6178-32-1
	Cresyl glycidyl ether (mixed isomers).....	26447-14-3
	<i>p</i> -Cumylphenyl glycidyl ether.....	61578-04-9
	Nitroaryl group containing no halogen or additional epoxide substituents:.....	
IV-B	<i>p</i> -Nitrophenyl glycidyl ether.....	5255-75-4
IV-C	Halogenated aryl group containing no nitro or additional epoxide substituents:.....	
	2,4-Dibromophenyl glycidyl ether.....	20217-01-0
	2,6-Dibromo-4-methylphenyl glycidyl ether.....	22421-59-6
	2,4-Dibromo-6-methylphenyl glycidyl ether.....	75150-13-9
V	<b>R = epoxy-substituted alkyl group:</b>	
V-A	Epoxy-substituted saturated alkyl group with no halogen substituent:.....	
	Ethylene glycol diglycidyl ether.....	2224-15-9
	Diglycidyl ether.....	<sup>1</sup> 2238-07-5
	1,4-Butanediol diglycidyl ether.....	<sup>1</sup> 2425-79-8
	Glycerol 1,3-diglycidyl ether.....	3568-29-4
	Glycerol triglycidyl ether.....	13236-02-7
	1,4-Bis(glycidyloxyethyl)cyclohexane.....	<sup>1</sup> 14228-73-0
	Neopentyl glycol diglycidyl ether.....	<sup>1</sup> 17557-23-2
	3-(2-Glycidyloxypropyl)-1-glycidyl-5,5-dimethylhydantoin.....	32568-69-1
	1,3-Bis(5,5-dimethyl-1-glycidylhydantoin-3-yl)-2-glycidyloxypropane.....	38304-52-8
	1,2,6-Hexanetriol triglycidyl ether.....	68959-23-9
V-B	Unsaturated epoxide-substituted alkyl group:.....	
	1,2,3-Propanetriyl ester of 12-(oxiranylmethoxy)-9-octadecanoic acid.....	<sup>1</sup> 74398-71-3
VI	<b>R = aryl group with additional epoxide end/or aryl group substituent(s):</b>	
VI-A	R contains two or more non-halogenated aryl groups with one or more additional epoxide substituents; not more than one epoxide substituent per aryl group:.....	
	Bisphenol A diglycidyl ether.....	<sup>1</sup> 1675-54-3
	2-Methylol-4,4'-isopropylidenediphenol diglycidyl ether.....	<sup>1</sup> 3188-83-8
	1,1,2,2-Tetra[ <i>p</i> -hydroxyphenyl]ethane tetraglycidyl ether.....	<sup>1</sup> 7328-97-4
	Bisphenol F diglycidyl ether.....	<sup>1</sup> 54208-63-8
	[Bis(4-glycidyloxyphenyl)]-(2-glycidyloxyphenyl)methane.....	<sup>1</sup> 67788-03-2



SUBCATEGORIZATION SCHEME FOR GLYCIDOL AND ITS DERIVATIVES—Continued<sup>1</sup>

Sub-category	Description of R or chemical name	CAS No.
	1,1,1-Tris(4-hydroxyphenyl)propane triglycidyl ether.....	<sup>1</sup> 68517-02-2
	2,2-Bis(p-2-glycidyloxy-3-butoxypropyloxy)phenyl]propane.....	71033-08-4
	2,2'-[1-(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediolyloxy-phenyleneoxymethylene)]bis (oxirane).....	4,1-phenylene-(1-methylethylidene)-4,1-phenyleneoxymethylene]bis (oxirane)..... 72319-24-5
VI-B	R contains two or more halogenated aryl groups with one or more additional epoxide substituents; not more than one epoxide substituent per aryl group:.....	
	2,2',6,6'-Tetrabromobisphenol A diglycidyl ether.....	3072-84-2
VI-C	Single aryl group with one or more additional epoxide substituent(s):.....	
	Resorcinol diglycidyl ether.....	<sup>1</sup> 101-90-6
	Hydroquinone diglycidyl ether.....	2425-01-6
	4-(Diglycidylamino)phenyl glycidyl ether.....	<sup>1</sup> 5026-7441
	2,6-Diglycidylphenyl glycidyl ether.....	13561-08-5
VII	<b>R = acyl group:</b>	
VII-A	Saturated aliphatic acyl group containing no additional epoxide substituent:.....	
	Glycidyl ester of neodecanoic acid.....	<sup>1</sup> 26761-45-5
VII-B	<i>alpha, beta</i> -Unsaturated aliphatic acyl group containing no additional epoxide substituent:.....	
	Glycidyl acrylate.....	<sup>1</sup> 106-90-1
	Glycidyl methacrylate.....	<sup>1</sup> 106-91-2
VII-C	Saturated aliphatic acyl group containing at least one additional epoxide substituent:.....	
	Diglycidyl ester of hexahydrophthalic acid.....	<sup>1</sup> 5493-45-8
VII-D	Aromatic acyl group containing at least one additional epoxide substituent:.....	
	Diglycidyl ester of phthalic acid.....	<sup>1</sup> 7195-45-1

<sup>1</sup>Believed by EPA to be in current production or importation, due to EPA's receipt of a report pursuant to the Inventory Update Rule (40 CFR 170.23), or due to Confidential Business Information obtained by EPA.

2. *Determining that requiring oncogenicity and mutagenicity testing of only one substance within a subcategory is appropriate.* As discussed in Unit III.F. of this preamble, EPA interprets TSCA section 4(a) to provide that, once EPA finds that a substance or a category of substances may present an unreasonable risk of injury to health or the environment, it may require the substance or each substance in the category to be tested for all health or environmental effects for which data are inadequate. Under this proposed rule, however, as a matter of testing policy to make testing less burdensome, EPA has selected a different approach. For mutagenicity and oncogenicity, EPA is proposing to require testing of one representative substance within the subcategory.

EPA believes that, for the purposes of this rule, extensive data bases that convincingly correlate chemical structure with observed health effects exist only for mutagenicity and oncogenicity. Therefore, EPA intends to regard the oncogenicity and mutagenicity data obtained for one representative member of a subcategory as sufficient to predict the mutagenic and oncogenic effects of all other members of that subcategory. Thus, if the data obtained from oncogenicity or mutagenicity testing of one representative member of a subcategory indicate a hazard to health, then EPA would regard all other members of that same subcategory as posing the same

hazard as the tested substance. EPA has not selected this approach for other health effects at this point in time because EPA has found the existing data bases relating structure and observed effects for other health effects less complete than those for oncogenicity and mutagenicity. As these databases increase, however, EPA may elect to use this SAR approach for other health effects.

3. *Selecting representative members of subcategories for testing.* EPA proposes to consider the following factors in the selection of a representative test substance: (a) Annual production volume; (b) exposure information; (c) test data on the substance itself; and (d) test data on close structural analogues. Although this proposed rule does not generally make explicit which substance would be selected as a test substance, using the above factors, EPA would make the selection and identify the representative test substance in the notification specified in Unit III.G. of this preamble. However, because the finding is proposed for the entire category and the proposed testing is triggered on a subcategory basis, all manufacturers and processors of substances within the subcategory would be legally subject to the rule and responsible for the required testing. For testing triggered by the annual production volume of the subcategory for health effects other than oncogenicity and mutagenicity, EPA

proposes, as a matter of policy, to select the member of the subcategory having the highest annual production volume, because EPA expects that glycidyls produced in greater quantities have greater exposure potential. EPA's selection of representative chemicals for testing in this proposal (see Table 5 in Unit V. of this preamble) reflects the application of this approach.

#### D. Proposed Criteria for Determining Oncogenic Potential of a Subcategory

EPA bases its concern for oncogenicity potential on the aggregate toxicological data available for all members of a given subcategory. A judgement that substances in a subcategory may have oncogenic potential would be made if, for one or more members of the given subcategory, the following types of oncogenicity or mutagenicity data exist:

(1) Positive or suggestive oncogenicity data on a subcategory member which are inadequate for risk assessment purposes.

(2) Positive or suggestive mutagenicity test data on subcategory members which, when considered in the aggregate on a weight-of-the-evidence basis, indicate a need for oncogenicity testing.

(3) Positive or suggestive oncogenicity or mutagenicity data on a close structural analogue of a subcategory member.



### *E. Proposed Criteria for Determining Mutagenic Potential of a Subcategory*

EPA bases its concern for mutagenic potential on the aggregate toxicological data available for all members of a given subcategory. A judgement that substances in a subcategory have specific mutagenic potential is proposed if, for one or more members of a given subcategory, the following types of mutagenicity or oncogenicity data exist:

(1) Mutagenicity data on subcategory members which, when considered in the aggregate on a weight-of-evidence basis indicate a need for further mutagenicity testing.

(2) Positive or suggestive oncogenicity data on a subcategory member.

(3) Positive or suggestive oncogenicity or mutagenicity data on a close structural analogue of a subcategory member.

Consideration of oncogenicity data on subcategory members and close structural analogues as a basis for requiring mutagenicity testing is based upon the well-established fact that many chemical substances exhibiting oncogenic activity also elicit mutagenic activity.

### *F. Types of Testing Required for Substances Based on Preliminary Hazard Data*

TSCA section 4(a) gives EPA the authority to require that testing be conducted, once EPA has made the requisite findings under section 4(a)(1)(A) or (B), to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to human health or the environment. Thus, EPA can require any or all testing necessary to determine the health or environmental effects for which EPA has determined there is an insufficiency of data or experience. There is no connection in TSCA between the "may present unreasonable risk" finding in TSCA section 4(a)(1)(A)(i) and the choice of tests to be conducted. Rather, the statute clearly relates the required testing to the data and experience which EPA has found to be insufficient to determine or predict the health or environmental effects.

Accordingly, the choice of appropriate tests in a test rule depends on EPA's

judgement about the insufficiency of data and experience under TSCA section 4(a)(1)(A)(ii) or (B)(ii) and EPA's determination whether the testing is "relevant to" an unreasonable risk determination. Thus, EPA may choose to require testing for a specific effect, even in the absence of information suggesting that the substance in question may cause the effect, if EPA determines that the test results would be relevant to an unreasonable risk determination for the activities involving that substance.

For the purposes of this rule, however, when EPA requires testing under TSCA section 4(a)(1)(A), as a matter of testing policy, and to reduce cost and burden, EPA is proposing to require health effects testing only for effects (or closely related effects) that are related to preliminary data suggesting adverse health effects on the particular substance (or, in the case of mutagenicity and oncogenicity, that are related to such preliminary data on members of the particular subcategory).

### *G. TSCA Section 8(a) Reporting and Triggering of Testing*

EPA intends to trigger some testing based only upon certain production levels being reached.

Under the authority of section 8(a) of TSCA, EPA is proposing that manufacturers (and importers) must provide annual reporting of the production and/or importation volumes for all of the substances meeting the definition of this chemical category which are currently or become listed on the public or confidential portion of the TSCA Chemical Substances Inventory. Using these data, EPA proposes to determine the annual aggregate production volumes for glycidol and the subcategories of its derivatives. Where the aggregate annual production volume of glycidol or a given subcategory reaches or exceeds 1 million pounds, or, subsequently, 10 million pounds, EPA proposes that it notify by certified letter or Federal Register notice all manufacturers, importers, and processors of glycidol or substances within that subcategory that the appropriate testing then required for that subcategory, described in Unit III.B. of this preamble, must be initiated with representative substances. EPA proposes to select the representative substances from subcategories as outlined in Unit III.C.3. of this preamble.

## **IV. Findings**

EPA is basing its proposed testing for members of the chemical category of glycidyls on the authority of sections 4(a)(1)(A) and 4(a)(1)(B) of TSCA through the use of TSCA section 26(c). Either finding is alone sufficient to support a test rule. Under TSCA section 26(c), EPA proposes to make section 4(a)(1)(A) and section 4(a)(1)(B) findings for the entire category of substances designated as glycidyls, encompassing the 66 discrete chemicals included on the TSCA public portion of the inventory, and any substance that is on the confidential portion of the inventory that would be included in the category, and any substance not yet produced that would fit the definition. This finding includes all monomeric glycidyls, including those which exist as monomeric byproducts of glycidyl polymer manufacture. EPA believes that this is an appropriate category of substances under section 26(c) because they are similar in molecular structure and in use (and are in many instances used interchangeably), and because their common epoxide functionality confers the potential for biological activity. This category is also "suitable for classification" because the ITC designated the category of glycidol and its derivatives for priority consideration for testing.

### *A. Findings Under TSCA Section 4(a)(1)(A)(i)*

Pursuant to section 4(a)(1)(A)(i) of TSCA, EPA finds that the manufacturing, processing, use, distribution in commerce, and disposal of all substances comprising the chemical category of "glycidyls", as defined in the sample regulatory text in this preamble, may present an unreasonable risk of injury to human health. The finding that this category of substances may present an unreasonable risk is based on their hazard potentials and potential exposures to the substances.

Many members of the glycidyls category are known to elicit adverse health effects. A support document (Ref. 3) discusses available toxicological data demonstrating that glycidyls are known to elicit the following adverse health effects: Oncogenicity, mutagenicity, developmental toxicity, adverse reproductive effects, subchronic toxicity, and chronic toxicity. The specific hazard data that support EPA's finding for the category are listed in the following Table 1:



TABLE 1.—DATA SUPPORTING THE TSCA SECTION 4(a)(1)(A) FINDINGS FOR GLYCIDYLS

Subcategory <sup>1</sup> or Substance	Type of Adverse Effects	Reference 3 section(s) supporting TSCA section 4(a)(1)(A)(i) findings
Glycidol (CAS No. 556-52-5) <sup>2</sup>	Oncogenicity..... Mutagenicity..... Reproductive toxicity..... Neurotoxicity.....	Addendum to II.1.a. II.1.a. and II.2. II.4.a. II.5.a.
Subcategory I-A.....	Oncogenicity..... Mutagenicity.....	II.2.b. II.2.b.
Subcategory I-C.....	Mutagenicity.....	II.2.c.
Subcategory I-D.....	Oncogenicity..... Mutagenicity.....	II.1.c. II.1.c.
Subcategory II-A.....	Mutagenicity.....	II.2.e.
Subcategory III-A.....	Oncogenicity..... Mutagenicity.....	II.2.f. II.2.f.
Subcategory IV-A.....	Mutagenicity.....	II.1.d. and II.2.g.
Subcategory V-A.....	Oncogenicity..... Mutagenicity.....	II.1.e. and II.2.i. II.1.e. and II.2.i.
Subcategory VI-A.....	Oncogenicity..... Mutagenicity.....	II.1.f. and II.2.j. II.1.f. and II.2.j.
Subcategory VI-C.....	Mutagenicity.....	II.1.g. and II.2.k.
Subcategory VII-B.....	Oncogenicity..... Mutagenicity.....	II.1.h. and II.2.m. II.1.h. and II.2.m.
Subcategory VII-C.....	Oncogenicity..... Mutagenicity.....	II.2.n. II.2.n.
Bisphenol A diglycidyl ether (CAS No. 1675-54-3).....	Developmental toxicity..... Reproductive toxicity..... Subchronic toxicity.....	II.3.d. II.4.g. II.6.k. and II.7.e. <sup>3</sup>
<i>n</i> -butyl glycidyl ether (CAS No. 2426-08-6).....	Reproductive toxicity..... Neurotoxicity..... Subchronic toxicity.....	II.4.c. II.5.b. II.6.d.
Alkyl (C <sub>8</sub> -C <sub>10</sub> ) glycidyl ether (CAS No. 68609-96-1).....	Reproductive toxicity..... Subchronic toxicity.....	II.4.d. II.6.e.
Allyl glycidyl ether (CAS No. 106-92-3).....	Reproductive toxicity..... Neurotoxicity.....	II.4.e. II.5.c.
3-(Trimethoxysilyl)propyl glycidyl ether (CAS No. 2530-83-8).....	Reproductive toxicity..... Neurotoxicity..... Subchronic.....	II.4.h. II.5.f. II.6.g.
Phenyl glycidyl ether (CAS No. 122-60-1).....	Reproductive toxicity..... Neurotoxicity.....	II.4.b. II.5.g.
<i>o</i> -Cresyl glycidyl ether (CAS No. 2210-79-9).....	Neurotoxicity.....	II.5.h.
1,4-Butanediol diglycidyl ether (CAS No. 2425-79-8).....	Neurotoxicity..... Subchronic toxicity.....	II.5.i. II.6.j.
Alkyl (C <sub>10</sub> -C <sub>14</sub> ) glycidyl ether (CAS No. 68081-84-5).....	Subchronic toxicity.....	II.6.f.
Glycidyl ester of neodecanoic acid (CAS No. 26761-45-5).....	Subchronic toxicity.....	II.6.m.
Glycidyl methacrylate (CAS No. 106-91-2).....	Subchronic toxicity.....	II.6.n. and II.7.g. <sup>3</sup>
Neopentyl glycol diglycidyl ether (CAS No. 17557-3-2).....	Subchronic toxicity.....	II.7.f. <sup>3</sup>

<sup>1</sup> Listed subcategories are defined in Unit III.B.1. of this preamble.

<sup>2</sup> Number contained in parentheses represents the Chemical Abstracts Service (CAS) registry number.

<sup>3</sup> Although flawed chronic data support the findings for this testing, because EPA believes that a well-conducted 90-day subchronic toxicity study is capable of detecting those effects (except for oncogenicity and certain other effects requiring long latency periods) which would be observed in a chronic toxicity study, EPA generally requires subchronic toxicity testing.

Many or all of these effects might be the result of the well-established alkylating potential of the glycidyl moiety shared by all members of the

glycidyls category, indicating that all members of the glycidyls category may pose a hazard to health.

The exposure component of this finding is described in Unit II.D. of this preamble and in two exposure support documents (Refs. 8 and 9). Briefly, these



data indicate that: (1) 36,697 workers are potentially exposed to glycidol; (2) 52,838 workers may be exposed to glycidyl ethers; (3) 42,469 workers may be exposed to glycidyl esters; and (4) 3 million people may be exposed to glycidyl ethers through the combined consumer and commercial use of epoxy resins.

Pursuant to section 4(a)(1)(A)(ii) and (iii) of TSCA, EPA finds that, for all substances comprising the glycidyls category, data are insufficient (for the reasons specified in Ref. 3) to determine or predict the effects of manufacturing, processing, distribution in commerce, or use of these substances on health, and that testing of these substances or appropriate representative substances is necessary to determine or predict their effects.

#### B. Findings Under TSCA Section 4(a)(1)(B)(i)

1. *Findings.* Pursuant to TSCA section 4(a)(1)(B)(i), EPA finds that the category of "glycidol and its derivatives" is or will be produced in substantial quantities. Specifically, EPA finds that 24 million pounds per year of these monomeric glycidyls are produced, excluding byproducts of glycidyl polymer manufacture.

The recent (usually data for 1985) aggregate annual production volumes for glycidol (CAS No. 556-52-5) and for each of the 21 subcategories of derivatives were determined by using data (Ref. 6) from reports submitted pursuant to the Inventory Update Rule (40 CFR 710.23) and from confidential current production information obtained by EPA. EPA recognizes that there are certain limitations in using the Inventory Update Reports for the purposes of this rulemaking (see 40 CFR 710.23 for details); however, EPA believes these data to be the most accurate figures currently available. As some of the 21 subcategories of glycidol derivatives contain only one chemical substance and, in some cases, all of the relevant production volume data for single-substance subcategories are confidential, all of the aggregate annual production volume data for glycidol and the 21 subcategories of its derivatives are being treated as TSCA Confidential Business Information (CBI). For the purposes of this rulemaking, EPA proposes to regard aggregate annual production volumes equal to or greater than 1 million pounds as a valid basis for making a finding of substantial production under TSCA section 4(a)(1)(B) for the reasons set forth in EPA's proposed TSCA section 4 policy proposed in the Federal Register on July 15, 1991 (56 FR 32294).

Further, pursuant to TSCA section 4(a)(1)(B)(i), EPA finds that there may be substantial exposure to the entire chemical category of glycidol and its derivatives from their manufacturing, processing, disposal, distribution in commerce, and use. Specifically, EPA finds that 24 million pounds per year of these monomeric glycidyls are produced (excluding byproduct manufacture; Ref. 6), that 36,697 workers may be exposed to glycidol, 52,838 workers may be exposed to monomeric glycidyl ethers, and 42,469 workers may be exposed to glycidyl esters each year (Ref. 8), that 3 million people may be exposed to glycidyl ethers through consumer and commercial use of epoxy resins (Ref. 9), and that the number of workers and/or consumers who may be exposed to glycidol and its derivatives is substantial under section 4(a)(1)(B). For the reasons discussed in the Federal Register notice explaining EPA's interpretation of its legal authority to require testing under TSCA section 4(a)(1)(B) (56 FR 32294, July 15, 1991), potential exposure to 1,000 workers and/or 10,000 consumers is considered to be potential substantial human exposure under TSCA section 4(a)(1)(B).

Alternatively, EPA proposes to make the section 4(a)(1)(B)(i) findings of substantial production and potential substantial human exposure for the entire category of glycidyls, limiting the category to the monomeric glycidyls, but including by-product glycidyl monomers present in various epoxy resins. On the basis of preliminary but convincing evidence (Ref. 7), EPA finds that over 343 million pounds of monomeric glycidyls are produced each year, when glycidyls present in resins are included in the total, and that this amount in this case is substantial under section 4(a)(1)(B) of TSCA. Also, EPA finds that 132,000 workers (Ref. 8) and 3 million consumers (Ref. 9) may be exposed to these monomeric glycidyls and that this number in this case is substantial under TSCA section 4(a)(1)(B). These amounts are substantial for the reasons set forth in the Federal Register notice explaining EPA's interpretation of its authority under TSCA section 4(a)(1)(B) (56 FR 32294, July 15, 1991).

In the notice articulating EPA's proposed criteria for interpreting its legal authority under TSCA section 4(a)(1)(B), EPA stated that it would continue to refine the criteria in specific rules. EPA believes that, for this category of chemical substances in which certain subcategory members are structurally similar, may be used interchangeably, and in which some individual members of the category are

produced in substantial quantities, it may be reasonable to require testing of subcategories of chemicals that collectively are or will be produced in quantities over 1 million pounds per year, and that either may be released to the environment in amounts greater than 1 million pounds per year or for which there may be exposure to over 1,000 workers, 10,000 consumers or 100,000 people, because if EPA made findings only on the individual substances that currently meet these thresholds, persons subject to the rule could simply switch to substances not in current production. Thus, EPA would have to propose an additional test rule. Theoretically, the persons subject to the rule could continue switching the substances they make and process, and EPA would never catch up. To inhibit this, EPA believes it is appropriate in this special case to make the findings for the subcategories using the same numerical thresholds as articulated for individual chemical substances and mixtures. However, for other chemical categories EPA may decide not to make the substantial exposure or quantities finding for the category as a whole, instead considering exposure on a subcategory or individual chemical basis.

Pursuant to section 4(a)(1)(B)(ii) and (iii) of TSCA, EPA finds that, for all substances comprising the glycidyls category, data are insufficient (for the reasons specified in Ref. 3) to determine or predict the effects of manufacturing, processing, distribution in commerce, or use of these substances on health, and that testing of these substances is necessary to determine or predict their effects.

For purposes of this rule, persons are invited to comment on how the TSCA section 4(a)(1)(B) criteria proposed in the Federal Register (56 FR 32294, July 15, 1991) apply to the TSCA section 4(a)(1)(B) findings made in this rule. EPA specifically solicits comment on whether EPA should use the same section numerical thresholds required to make a section 4(a)(1)(B) finding for a subcategory of chemicals as the numerical thresholds used for individual chemicals, or instead require higher thresholds for subcategories. When this rule is promulgated, EPA will address all comments on the proposed criteria that are relevant to this rule as well as the comments on this proposed rule.

2. *Choices on testing of substances for which TSCA section 4(a)(1)(B) findings are made—*a. *Testing batteries.* Once EPA has made the above findings under TSCA section 4(a)(1)(B)(i), EPA may require any health effects testing for



which EPA finds that there are insufficient data and for which testing is necessary to determine whether the substance presents or does not present an unreasonable risk to health. EPA has, however, taken into account the ability of manufacturers to pay for such testing and has decided not to require the entire battery of tests. Instead, EPA is proposing to trigger testing from the production volumes of glycidol and of the members of the various subcategories of glycidyls. Once the production volume of glycidol or a subcategory of glycidyls reaches 1 million pounds per year, a specified battery of tests would be triggered. Once the production volume reaches 10 million pounds per year, a more extensive battery of tests would be triggered. These production volumes are used as a rough measure of the affordability of testing.

b. *Test substance.* Based on the findings made for the entire category, all manufacturers and processors of glycidyls would be subject to this rule, but one substance within a subcategory would be designated as the test substance for the testing required as a result of the section 4(a)(1)(B) finding. Thus, all of the manufacturers and

processors of substances within the subcategory would be responsible for the testing costs, although not every member of a subcategory would be tested. The purpose of proceeding this way is twofold. First, it will take into account the affordability of testing. Second, because some of the substances within this category are used interchangeably, it would prevent manufacturers and processors from manipulating production among the various members of a subcategory to avoid paying for testing. Unit III.C.3. of this preamble outlines the method of selecting the proposed test substance within each subcategory.

If at the time subcategory testing is triggered the specified test substance is not commercially available, then for testing for all effects, except mutagenicity and oncogenicity, the highest production substance on the date the subcategory meets the production trigger would be selected by EPA as the test substance for the subcategory testing. EPA will consider available mutagenicity and oncogenicity test data on subcategory members and close structural analogues, as well as production data, in selecting test substances for these two health effects.

## V. Proposed Rule

### A. Testing Proposed to be Triggered as a Result of Data Submitted Under Section 8(a) of TSCA

EPA is proposing under section 4(a)(1)(B) of TSCA the tests listed in Tables 2 and 3 elsewhere in this preamble for glycidol or for a representative member of each subcategory which meets certain production volume criteria. EPA is proposing the oral route of administration for all whole-animal studies, and specifying gavage administration for the oncogenicity, the subchronic toxicity, the *in vivo* cytogenetics, the developmental toxicity (both standard and screening tests), the reproductive toxicity, the dominant lethal, the heritable translocation, and the MBSL or MVSL tests, as discussed in Unit V.B. of this preamble.

To mitigate testing costs, EPA is proposing to require the testing listed in the following Table 2 for glycidol or for a representative member of any subcategory for which the annual reports, which EPA is proposing under section 8(a) of TSCA, indicate an aggregate annual subcategory production volume of at least 1 million pounds but less than 10 million pounds.

TABLE 2.—PROPOSED TESTS, TEST STANDARDS, AND REPORTING REQUIREMENTS FOR GLYCIDOL OR FOR SUBCATEGORIES HAVING ANNUAL AGGREGATE PRODUCTION/IMPORTATION VOLUMES OF AT LEAST 1 MILLION BUT LESS THAN 10 MILLION POUNDS

Proposed test	Proposed test standard (40 CFR part 798)	Reporting requirements for final report <sup>1</sup>
90-Day oral subchronic toxicity in rats.....	§ 798.2650.....	12 months
Chernoff screening test for developmental toxicity in the rat.....	§ 798.4420.....	12 months
Ames gene mutation test.....	§ 798.5265.....	9 months
Mouse lymphoma L5178Y TK ± gene mutation test.....	§ 798.5300.....	10 months
In vitro cytogenetics test with Chinese hamster ovary cells.....	§ 798.5375.....	10 months
In vivo cytogenetics test in the mouse.....	§ 798.5385.....	14 months
Oral subchronic (90-day) neurotoxicity testing in rats:		
Functional observation battery.....	§ 798.6050.....	18 months
Neuropathology.....	§ 798.6400.....	18 months
Motor activity.....	§ 798.6200.....	18 months

<sup>1</sup> The numbers of months, calculated from the date of EPA's notification of manufacturers and importers that testing should be initiated, by which a final report must be submitted to EPA. Interim (6-month) progress reports would be required for all tests having final report deadlines of 9 months or greater.

The proposed test standard for each test appears in 40 CFR part 798. EPA is proposing to notify by certified letter or Federal Register notice all manufacturers and importers of glycidol or of all substances contained in a given subcategory whose annual production meets the proposed trigger that testing of a representative substance will be required. At the same time, EPA would provide affected persons a limited time to submit new data not available at the time of this rulemaking showing that some or all of the tests have already

been performed. Following review of the new data, and according to the procedures presented in Unit III.C.3. of this preamble, EPA would then notify manufacturers and importers to initiate testing with specific test substances. With respect to mutagenicity testing, all four tests listed in Table 2 are to be conducted, but EPA is not proposing in this rule the triggering of additional testing for either mutagenicity or oncogenicity from these test results. All manufacturers and processors of any

substance within the subcategory would be required to pay for the testing.

The proposed reporting requirements would be calculated from the date of notification. Six-month interim progress reports are proposed for all tests of 9 months or more in duration. EPA proposes to identify the representative chemical from the subcategory to be tested, using the criteria in Unit III.C.3. of this preamble. Table 2 lists the proposed tests, test standards, and reporting requirements for glycidol or for subcategories having future annual



aggregate production/importation volumes of at least 1 million but less than 10 million pounds.

For glycidol or for subcategories

which, based on TSCA section 8(a) reports, attain an annual aggregate subcategory production (including importation) volume of 10 million

pounds or greater, EPA is proposing the specific tests, test standards, and reporting requirements presented in the following Table 3:

TABLE 3.—PROPOSED TESTS, TEST STANDARDS, AND REPORTING REQUIREMENTS FOR GLYCIDOL OR FOR SUBCATEGORIES HAVING FUTURE ANNUAL AGGREGATE PRODUCTION/IMPORTATION VOLUMES OF 10 MILLION POUNDS OR GREATER

Proposed test	Proposed test standard (40 CFR part 798)	Reporting Requirements for final reports <sup>1</sup>
Oral oncogenicity bioassays in rats and mice and associated 90-day oral subchronic studies.	§ 798.3300 and § 798.2650	53 months
Developmental toxicity testing in rats and mice.....	§ 798.4900	12 months
Two-generation reproductive toxicity testing in rats.....	§ 798.4700	29 months
Acute oral neurotoxicity testing in rats:		
Functional observation battery.....	§ 798.6050	6 months
Motor activity studies.....	§ 798.6200	6 months
Oral subchronic (90-day) neurotoxicity testing in rats:		
Functional observation battery.....	§ 798.6050,	18 months
Motor activity studies.....	§ 798.6200	18 months
Neuropathology.....	§ 798.6400	18 months
Ames gene mutation test.....	§ 798.5265	9 months
Mouse lymphoma L5178Y TK ± gene mutation test.....	§ 798.5300	19 months <sup>2</sup> (10 months) <sup>3</sup>
Sex-linked recessive lethal gene mutation test in <i>Drosophila</i> .....	§ 798.5275	31 months <sup>2</sup> (12 months) <sup>3</sup>
Mouse visible specific locus gene mutation test or Mouse biochemical specific locus gene mutation test.	§ 798.5200 or § 798.5195	51 months <sup>4</sup> (either test)
In vitro cytogenetics test with Chinese hamster ovary cells.....	§ 798.5375	10 months
In vivo cytogenetics test in the mouse.....	§ 798.5385	24 months <sup>2</sup> (14 months) <sup>3</sup>
Dominant lethal cytogenetics test in the mouse.....	§ 798.5450	36 months <sup>2</sup> (12 months) <sup>3</sup>
Heritable translocation cytogenetics test in the mouse.....	§ 798.5460	25 months <sup>4</sup>

<sup>1</sup> The number of months, calculated from the date of EPA's notification of manufacturers and importers that testing should be initiated, by which a final report must be submitted to EPA. Interim (6-month) progress report would be required for all tests having final report deadlines of 9 months or greater.

<sup>2</sup> If required due to results of lower-tier testing, the number of months, calculated from the date of EPA's notification of manufacturers and importers that the initial lower-tier testing would be conducted, by which a final report must be submitted to EPA. Interim (6-month) progress reports would be required for all tests having final report deadlines of 9 months or greater.

<sup>3</sup> The number of months allowed for the given test, not including the time allowed for previous mutagenicity testing.

<sup>4</sup> The number of months by which the final report is due to EPA, calculated from the date of EPA's notification of manufacturers and importers that testing must be initiated, based upon EPA's review of all of the available mutagenicity data.

For mutagenicity testing, EPA proposes using the same test sequences and triggering of tests (including oncogenicity bioassay testing) as discussed in Unit V.B.2. of this preamble. EPA proposes to notify all manufacturers and importers of glycidol or of substances contained in such a subcategory that the subcategory production/importation trigger has been reached and that testing of a

representative substance will be required. At that time, EPA would provide affected persons a limited time to submit new data not available at the time of this rulemaking showing that some or all of the tests have already been performed. After review of the new data, and according to the procedures presented in Unit III.C.3. of this preamble, EPA would then notify manufacturers and importers that

testing should be initiated with specific test substances.

#### *B. Proposed Immediately-Required Testing and Test Standards Based on Available Hazard and/or Production Data*

The proposed immediately-required testing and test standards for glycidyls, based on available hazard and/or production data, are summarized in the following Table 4:

TABLE 4.—PROPOSED IMMEDIATELY-REQUIRED TESTING AND TEST STANDARDS FOR GLYCIDYLS (NOT INCLUDING FUTURE TESTING TRIGGERED BY SUBCATEGORY PRODUCTION VOLUME)

Proposed test(s)	Subcategory	Test substance	Required to test <sup>1</sup>	Comments
<b>Oncogenicity:</b>				
1. Oral bioassays in rats and mice (§ 798.3300).	VI-A	Bisphenol A diglycidyl ether (CAS No. 1675-54-3)	S	
2. 90-Day oral subchronic toxicity tests in rats and mice (§ 798.2650).				



TABLE 4.—PROPOSED IMMEDIATELY-REQUIRED TESTING AND TEST STANDARDS FOR GLYCIDYLS (NOT INCLUDING FUTURE TESTING TRIGGERED BY SUBCATEGORY PRODUCTION VOLUME)—Continued

Proposed test(s)	Subcategory	Test substance	Required to test <sup>1</sup>	Comments
<b>Mutagenicity:</b> Tiered tests for gene mutation and chromosomal aberration. (See comments column of the table for entry assay into each tier.) As noted, in some cases only specific tests are required. Representative test substances for subcategories tested based on adverse hazard data or for subcategories having annual aggregate production volumes equal to or greater than 10 million pounds are subject to all triggered mutagenicity testing shown in Charts 1 and 2 in Unit V.B.2. of this preamble for both testing tiers. As noted, testing for representative numbers of subcategories having aggregate annual production volumes of 1 million pounds or more, but less than 10 million pounds, currently includes only the four mutagenicity tests listed. Further testing would be required when subcategory production volume reaches or exceeds 10 million pounds.				
	None	Glycidol (CAS No. 556-52-5)	I	GM: MSL and CA: DL
	I-A	<i>n</i> -Butyl glycidyl ether (CAS No. 2426-08-6)	S	GM: SLRL and CA: DL
	I-C	Allyl glycidyl ether (CAS No. 106-92-3)	S*	GM: MSL and CA: DL
	I-D	2-Ethylhexyl glycidyl ether (CAS No. 2461-15-6)	S*	GM: MC and CA: MC
	II-A	Alkyl (C <sub>12</sub> -C <sub>14</sub> ) glycidyl ether (CAS No. 68609-97-2)	S	GM: Ames, CA: MC and In Vivo, only
	III-A	3-(Trimethoxysilyl)propyl glycidyl ether (CAS No. 2530-83-8)	S*	GM: SLRL and CA: MC
	IV-A	<i>o</i> -Cresyl glycidyl ether (CAS No. 2210-79-9)	S	GM: SLRL and CA: None
	V-A	1,4-Butanediol diglycidyl ether (CAS No. 2425-79-8)	S	GM: MSL and CA: DL
	V-B	1,2,3-Propanetriyl ester of 12-(oxiranylmethoxy)-9-octadecenoic acid (CAS No. 74398-71-3)	S*	GM: Ames and MC, only; CA: MC and In Vivo, only
	VI-A	Bisphenol A diglycidyl ether (CAS No. 1675-54-3)	S	GM: MC and CA: DL
	VI-C	4-(Diglycidylamino)phenyl glycidyl ether (CAS No. 5026-74-4)	S	GM: MSL and CA: DL
	VII-A	Glycidyl ester of neodecanoic acid (CAS No. 26761-45-5)	S*	GM: Ames and MC, only; CA: MC and In Vivo, only
	VII-B	Glycidyl acrylate (CAS No. 106-90-1)	S	GM: SLRL and CA: DL
	VII-C	Diglycidyl ester of hexahydrophthalic acid (CAS No. 5493-45-8)	S*	GM: SLRL and CA: DL
<b>Developmental Toxicity:</b> See Comments Column of the Table for requirements for full test (§ 798.4900) in rats and mice or the Chernoff screening test (§ 798.4420) in rats.				
	I-A	<i>n</i> -Butyl glycidyl ether (CAS No. 2426-08-6)	S	Screening test.
	I-C	Allyl glycidyl ether (CAS No. 106-92-3)	S*	Screening test.
	II-A	Alkyl (C <sub>12</sub> -C <sub>14</sub> ) glycidyl ether (CAS No. 68609-97-2)	S	Screening test.
	III-A	3-(Trimethoxysilyl)propyl glycidyl ether (CAS No. 2530-83-8)	S*	Screening test.
	IV-A	<i>o</i> -Cresyl glycidyl ether (CAS No. 2210-79-9)	S	Screening test.
	V-B	1,2,3-Propanetriyl ester of 12-(oxiranylmethoxy)-9-octadecenoic acid (CAS No. 74398-71-3)	S*	Screening test.
	VI-A	Bisphenol A diglycidyl ether (CAS No. 1675-54-3)	S	Full test <sup>a</sup>
	VII-A	Glycidyl ester of neodecanoic acid (CAS No. 26761-45-5)	S*	Screening test
	VII-B	Glycidyl methacrylate (CAS No. 106-91-2)	S	Screening test.
<b>Reproductive toxicity:</b>				



TABLE 4.—PROPOSED IMMEDIATELY-REQUIRED TESTING AND TEST STANDARDS FOR GLYCIDYLS (NOT INCLUDING FUTURE TESTING TRIGGERED BY SUBCATEGORY PRODUCTION VOLUME)—Continued

Proposed test(s)	Subcategory	Test substance	Required to test <sup>1</sup>	Comments
Oral two-generation reproduction study (§ 798.4700) in rats..	None	Glycidol (CAS No. 556-52-5)	I	
	I-A	<i>n</i> -Butyl glycidyl ether (CAS No. 2426-08-6)	I	
	I-A	Alkyl (C <sub>8</sub> -C <sub>18</sub> ) glycidyl ether (CAS No. 68609-96-1)	I	
	I-C	Allyl glycidyl ether (CAS No. 106-92-3)	I	
	III-A	3-(Trimethoxysilyl)propyl glycidyl ether (CAS No. 2530-83-8)	I	
	IV-A	Phenyl glycidyl ether (CAS No. 122-60-1)	I	
	VI-A	Bisphenol A diglycidyl ether (CAS No. 1675-54-3)	S	
<b>Neurotoxicity (in rats):</b>				
1. Acute and Subchronic (§ 798.6050).....				
2. Acute and Subchronic (§ 798.6200).....				
3. Subchronic (§ 798.6400) See Comments Column of the table for determination if only subchronic tests are required, or if both subchronic and acute tests are required..	None	Glycidol (CAS No. 556-52-5)	I	Subchronic and acute
	I-A	<i>n</i> -Butyl glycidyl ether (CAS No. 2426-08-6)	I/S	Subchronic and acute
	I-C	Allyl glycidyl ether (CAS No. 106-92-3)	I/S*	Subchronic and acute
	II-A	Alkyl (C <sub>12</sub> -C <sub>14</sub> ) glycidyl ether (CAS No. 68609-97-2)	S	Subchronic only
	III-A	3-(Trimethoxysilyl)propyl glycidyl ether (CAS No. 2530-83-8)	I/S*	Subchronic and acute
	IV-A	Phenyl glycidyl ether (CAS No. 122-60-1)	I/S	Subchronic and acute
	IV-A	<i>o</i> -Cresyl glycidyl ether (CAS No. 2210-79-9)	I/S	Subchronic and acute
	V-A	1,4-Butanediol diglycidyl ether (CAS No. 2425-79-8)	I	Subchronic and acute
	V-B	1,2,3-Propanetriyl ester of 12-(oxiranyl-methoxy)-9-octadecenoic acid (CAS No. 74398-71-3)	S*	Subchronic only
	VI-A	Bisphenol A diglycidyl ether (CAS No. 1675-54-3)	S	Subchronic and acute
	VII-A	Glycidyl ester of neodecanoic acid (CAS No. 26761-45-5)	S*	Subchronic only
	VII-B	Glycidyl methacrylate (CAS No. 106-91-2)	S	Subchronic only
Oral Subchronic (90-Day) Toxicity in rat: (§ 798.2650)	I-A	<i>n</i> -Butyl glycidyl ether (CAS No. 2426-08-6)	I	
	I-A	Alkyl (C <sub>8</sub> -C <sub>18</sub> ) glycidyl ether (CAS No. 68609-96-1)	I	
	I-A	<i>tert</i> -butyl glycidyl ether (CAS No. 7665-72-7)	S	
	I-C	Allyl glycidyl ether (CAS No. 106-92-3)	S*	
	II-A	Alkyl (C <sub>10</sub> -C <sub>16</sub> ) glycidyl ether (CAS No. 68081-84-5)	I	
	II-A	Alkyl (C <sub>12</sub> -C <sub>14</sub> ) glycidyl ether (CAS No. 68609-97-2)	S	
	III-A	3-(Trimethoxysilyl)propyl glycidyl ether (CAS No. 2530-83-8)	S*	
	IV-A	<i>o</i> -Cresyl glycidyl ether (CAS No. 2210-79-9)	S	
	V-A	1,4-Butanediol diglycidyl ether (CAS No. 2425-79-8)	I	
	V-A	Neopentyl glycol diglycidyl ether (CAS No. 17557-23-2)	I	
	V-B	1,2,3-Propanetriyl ester of 12-(oxiranyl-methoxy)-9-octadecenoic acid (CAS No. 74398-71-3)	S*	
	VII-A	Glycidyl ester of neodecanoic acid (CAS No. 26761-45-5)	S*	
	VII-B	Glycidyl methacrylate (CAS No. 106-91-2)	I	
	VII-B	Glycidyl acrylate (CAS No. 106-90-1)	S	

<sup>1</sup> Abbreviations used to indicate persons required to test: S indicates that manufacturers and importers of all substances in the subcategory are required to test. S\* indicates that, although all manufacturers and importers of all substances in the subcategory are required to test, the subcategory currently contains only one substance thought to be currently imported or produced. I indicates that manufacturers and importers of the given substance only are required to test. I/S or I/S\* indicates that, for neurotoxicity testing only, manufacturers and importers of all substances in the subcategory are required to conduct the subchronic tests, but only the manufacturers and importers of the specific test substances, which are also subject to testing based on preliminary data, are required to conduct the acute tests.



<sup>2</sup> Abbreviations used for mutagenicity testing: GM is gene mutation. CA is chromosomal aberration. MSL is the mouse visible or biochemical specific locus assay. DL is the rodent dominant lethal assay. Ames is the gene mutation test utilizing *Salmonella typhimurium*. MC indicates an *in vitro* assay with mammalian cells. SLRL is the sex-linked recessive lethal assay in *Drosophila melanogaster*. *In Vivo* indicates an assay in an intact mammal.

<sup>3</sup> Due to a valid dermal developmental toxicity study in rabbits, only a complete oral study in rats is required.

This table includes individual substances for which EPA has preliminary adverse hazard data for various health effects, as well as subcategories (and selected representative test substances for which EPA has preliminary adverse mutagenicity or oncogenicity data. This table also includes subcategories (and selected representative test substances) which at this time have reached either of the production volume testing triggers (1 million or 10 million pounds annual aggregate subcategory production volume). In the future, this table will change as various subcategories meet the production volume testing triggers, becoming subject to the testing batteries proposed at each production level.

EPA is proposing that the health effects testing be conducted in accordance with specific guidelines set forth in 40 CFR part 798, modified as to route of administration as discussed below, and enumerated in Table 4 as the test standards. The TSCA health effects testing guidelines specify generally accepted minimal conditions for determining the health effects for substances to which humans are expected to be exposed. EPA is proposing that all whole-animal studies be conducted in rats and mice, because EPA believes that the relevant historical data bases (used for comparative purposes) for these studies are the largest for these two species with respect to glycidyls. Similarly, EPA is

proposing specific insect species and mammalian cell lines proposed for the mutagenicity testing because of their large historical data bases. EPA solicits comment on this approach.

1. **Oncogenicity.** As shown in Table 4, EPA is proposing that a representative member of subcategory VI-A, bisphenol A diglycidyl ether, be designated as the test substance for oncogenicity testing in both rats and mice. As discussed in a support document (Ref. 3), EPA has preliminary adverse data for the following subcategories in addition to subcategory VI-A: subcategories I-A, I-D, III-A, V-A, VII-B, and VII-C. However, evaluation of the affordability of testing, included in the economic analysis for this proposed rule (Ref. 14), leads EPA to propose that the testing of representative members of these other six subcategories be delayed until the annual aggregate production of a subcategory reaches 10 million pounds or greater, as shown by data EPA will receive from the proposed glycidyls TSCA section 8(a) reporting rule. (See Units III.B. and III.G. of this preamble) EPA proposes (as discussed in Unit III. G. of this preamble) to notify by certified letter or Federal Register notice all manufacturers (including importers) and processors of substances contained in any of these six subcategories, when the 10 million pound trigger is reached, that bioassay testing (together with other triggered tests) shall be initiated

for the subcategory with an EPA-designated test substance.

EPA has selected the representative member of subcategory VI-A for testing as described in Unit III.C.3. of this preamble. The substance selected for testing from subcategory VI-A has a very high annual production volume and has exhibited mutagenic and oncogenic activity (Ref. 3).

EPA is proposing that all oncogenicity bioassay testing be conducted by gavage according to 40 CFR 798.3300, and that the subchronic (90-day) studies be conducted by gavage in accordance with 40 CFR 798.2650. To ensure a comprehensive evaluation of chronic effects, EPA considered proposing the combined chronic toxicity/oncogenicity TSCA Health Effect Testing Guideline (40 CFR 798.3320) as the test standard for the oncogenicity testing. However, EPA has decided to propose the combination of the (oral) oncogenicity testing guideline (40 CFR 798.3300) and the subchronic oral toxicity testing guideline (40 CFR 798.2650) as the test standard for the oncogenicity testing. EPA is soliciting public comment on this issue in Unit VI. of this preamble.

2. **Mutagenicity.** The proposed immediately-required mutagenicity testing and test standards for the chemical category of glycidyls is summarized in the following Table 5, which presents the two types of mutagenicity testing proposed in this rule.

TABLE 5.—PROPOSED ENTRY ASSAY FOR IMMEDIATELY-REQUIRED MUTAGENICITY TESTING AND TEST STANDARDS FOR GLYCIDYLS (NOT INCLUDING FUTURE SUBCATEGORY PRODUCTION VOLUME-TRIGGERED TESTING)

Subcategory <sup>1</sup>	Subcategory member selected for testing	Entry assays		Species or system	
		Gene mutation <sup>2</sup>	Chromosomal aberration <sup>3</sup>	Gene mutation	Chromosomal aberration
None	Glycidol (CAS No. 556-52-5)	Mouse visible specific locus (§ 798.5200 <sup>4</sup> or biochemical specific locus (§ 798.5195)	Rodent dominant lethal (§ 798.5450)	Mouse	Mouse
I-A	n-butyl glycidyl ether (CAS No. 2426-08-6)	<i>Drosophila</i> sex-linked recessive lethal (§ 798.5275)	Rodent dominant lethal (§ 798.5450)	<i>Drosophila melanogaster</i>	Mouse
I-C	Allyl glycidyl ether (CAS No. 106-92-3)	Mouse visible specific locus (§ 798.5200) or biochemical specific locus (§ 798.5195)	Rodent dominant lethal (§ 798.5450)	Mouse	Mouse
I-D	2-Ethylhexyl glycidyl ether (CAS No. 2461-15-6)	Mammalian cells in culture (§ 798.5300)	<i>In vitro</i> cytogenetics (§ 798.5375)	Mouse lymphoma L5178Y TK ±	Chinese hamster ovary cells
II-A	Alkyl (C <sub>12</sub> -C <sub>14</sub> ) glycidyl ether <sup>5</sup> (CAS No. 68609-97-2)	Ames test (§ 798.5265)	<i>In vitro</i> cytogenetics (§ 798.5375) <i>In vivo</i> cytogenetics (§ 798.5385)	<i>Salmonella typhimurium</i>	Chinese hamster ovary cells Mouse
III-A	3-(Trimethoxysilyl)propyl glycidyl ether (CAS No. 2530-83-8)	<i>Drosophila</i> sex-linked recessive lethal (§ 798.5275)	<i>In vitro</i> cytogenetics (§ 798.5375)	<i>Drosophila melanogaster</i>	Chinese hamster ovary cells



TABLE 5.—PROPOSED ENTRY ASSAY FOR IMMEDIATELY-REQUIRED MUTAGENICITY TESTING AND TEST STANDARDS FOR GLYCIDYLS (NOT INCLUDING FUTURE SUBCATEGORY PRODUCTION VOLUME-TRIGGERED TESTING)—Continued

Subcategory	Subcategory member selected for testing	Entry assays		Species or system	
		Gene mutation <sup>a</sup>	Chromosomal aberration <sup>b</sup>	Gene mutation	Chromosomal aberration
IV-A	o-Cresyl glycidyl ether <sup>c</sup> (CAS No. 2210-79-9)	<i>Drosophila</i> sex-linked recessive lethal (§ 798.5275)	None	<i>Drosophila melanogaster</i>	None
V-A	1,4-Butanediol diglycidyl ether (2425-79-8)	Mouse visible specific locus (§ 798.5200) or biochemical specific locus (§ 798.5195)	Rodent dominant lethal (§ 798.5450)	Mouse	Mouse
V-B <sup>d</sup>	1,2,3-Propanetriyl ester of 12-(Oxiranylmethoxy)-9-octadecanoic acid (CAS No. 74398-71-3)	Ames test (§ 798.5265)	In vitro cytogenetics (§ 798.5375)	<i>Salmonella typhimurium</i>	Chinese hamster ovary cells
		Mammalian Cells in culture (§ 798.5300)	In vivo cytogenetics (§ 798.5385)	Mouse Lymphoma L5/178Y TK ±	Mouse
VI-A	Bisphenol A diglycidyl ether (CAS No. 1675-54-3)	Mammalian Cells in culture (§ 798.5300)	Rodent dominant lethal (§ 798.5450)	Mouse Lymphoma L5/178Y TK ±	Mouse
VI-C	4-(Diglycidylamino)phenyl glycidyl ether (CAS No. 5026-74-4)	Mouse visible specific locus (§ 798.5200) or biochemical specific locus (§ 798.5195)	Rodent dominant lethal (§ 798.5450)	Mouse	Mouse
VII-A <sup>e</sup>	Glycidyl ester of neodecanoic acid (CAS No. 26761-45-5)	Ames test (§ 798.5265)	In vitro cytogenetics (§ 798.5385)	<i>Salmonella typhimurium</i>	Chinese hamster ovary cells
		Mammalian Cells in culture (§ 798.5300)	In vivo cytogenetic (§ 798.5375)	Mouse Lymphoma L5/178Y TK ±	Mouse
VII-B	Glycidyl acrylate (CAS No. 106-90-1)	<i>Drosophila</i> Sex-linked recessive lethal (§ 798.5275)	Rodent dominant lethal (§ 798.5450)	<i>Drosophila melanogaster</i>	Mouse
VII-C	Diglycidyl ester of hexahydrophthalic acid (CAS No. 5493-45-8)	<i>Drosophila</i> Sex-linked recessive lethal (§ 798.5275)	Rodent dominant lethal (§ 798.5450)	<i>Drosophila melanogaster</i>	Mouse

<sup>a</sup>Subcategories are defined in Unit III.C.1. of this preamble.

<sup>b</sup>Beginning with the gene mutation assay listed, the test substance is to be tested in the tiered battery of tests for gene mutation described in Unit V.B.2. of this preamble. All whole-animal testing is to be conducted by oral administration.

<sup>c</sup>Beginning with the chromosomal aberration assay listed, the test substance is to be tested in the tiered sequence of tests for chromosomal aberration described in Unit V.A.2. of this preamble. All whole-animal testing is to be conducted by oral administration.

<sup>d</sup>Identifies the proposed test guideline as it appears in 40 CFR part 798, proposed as the test standard for this rule.

<sup>e</sup>The available health effects data for Subcategory II-A contained in Section II.2.e. of a support document (Ref. 3) indicate that the representative substance should be tested for gene mutation (complete test sequence). No relevant data were available for Subcategory II-A with respect to eliciting chromosomal aberrations. As described in Unit III.B. of this preamble, the representative substance from Subcategory II-A (having an annual aggregate production volume of greater than 1 million but less than 10 million pounds) is proposed under section 4(a)(1)(B) of TSCA to be tested in the first-tier tests only for eliciting chromosomal aberrations.

<sup>f</sup>o-Cresyl glycidyl ether is the representative substance selected from Subcategory IV-A for mutagenicity testing. As described in Table 1 of Unit IV.A of this preamble, a finding under section 4(a)(1)(A) has been made for this subcategory for gene mutation testing; thus, o-cresyl glycidyl ether is subject to the full sequence of tests employed for this effect, beginning with the test indicated. On the other hand, no finding under TSCA section 4(a)(1)(A) could be made for this subcategory for chromosomal aberration testing. As described in Unit III.F. of this preamble, a representative substance from Subcategory IV-A (having an annual production and/or importation volume of greater than 1 million but less than 10 million pounds) would normally be subject to the first-tier sequence of tests for chromosomal aberration by a finding under section 4(a)(1)(B) of TSCA. However, as presented in Section II.2.f. of a support document (Ref. 5), the available data indicate that members of this subcategory have little potential for eliciting chromosomal effects. Therefore, no tests for chromosomal effects are required for o-cresyl glycidyl ether.

<sup>g</sup>As described in Unit III.F. of this preamble, representative substances from Subcategories V-B and VII-A (having an annual aggregate production and/or importation volume of greater than 1 million but less than 10 million pounds) are required to be tested in the first tiers only of the test sequences for gene mutation and chromosomal aberration. No further mutagenicity or oncogenicity testing is triggered from the results of these tests.

For representative test substances for subcategories whose testing is proposed on the basis of hazard information or for subcategories having an annual aggregate production volume of 10 million pounds or greater, Table 5 presents the entry assay into each of the two mutagenicity testing batteries for gene mutation and chromosomal aberration described in Charts 1 and 2 of Unit V.B.2. of this preamble. These test substances are subject to all of the triggered mutagenicity testing depicted in these charts.

For representative test substances of subcategories having annual aggregate production volumes of 1 million pounds

or more, but less than 10 million pounds, Table 5 describes the four mutagenicity assays proposed. The results from these four tests would not trigger further mutagenicity or oncogenicity testing. However, the subcategory would be subject to further mutagenicity testing, as well as oncogenicity testing, whenever its annual aggregate production volume reaches or exceeds 10 million pounds.

The general batteries of tiered tests usually employed by EPA in assessing the mutagenic (both gene mutation and chromosomal aberration) potential of chemical substances, which are included in modified form in this

proposed test rule, have been previously described in proposed rules issued by EPA for mesityl oxide (48 FR 30699, July 5, 1983), cresols (48 FR 31812, July 11, 1983), and ethyltoluenes, trimethylbenzenes, and C9 aromatic hydrocarbon fraction (43 FR 23088, May 23, 1983), and are more completely described in the final Phase I test rules for mesityl oxide (50 FR 51857, December 20, 1985) and C9 aromatic hydrocarbon fraction (50 FR 20622, May 17, 1985).

EPA's responses to comments on the tiered testing batteries for gene mutation testing and for cytogenetics testing may be found in the final Phase I test rules



for the C9 aromatic hydrocarbon fraction and mesityl oxide. Further, while EPA recognizes that there is, as yet, no single generally accepted methodology for estimating human risk from mutagenic agents, it is EPA's view that appropriate methodologies do exist that, in combination, are usable for risk estimation. Therefore, EPA concludes that it is appropriate at this time to obtain mutagenicity data on certain glycidyls that will allow it to estimate mutagenic risk for regulatory purposes.

EPA is proposing a tiered testing approach to evaluate whether certain glycidyls elicit heritable gene mutations. If after a review of all relevant information, including positive results in the sex-linked recessive lethal gene mutation test in *Drosophila melanogaster*, EPA determines that further gene mutation testing is necessary, EPA would require either a mouse visible specific locus (MVSL) test or a mouse biochemical specific locus (MBSL) test. EPA believes that the MVSL or MBSL is necessary, when this lower-tier test is positive, to establish definitively whether a substance can elicit heritable gene mutations. Under the approach proposed, EPA would

consider the results of all of the lower-tier tests in a review, together with other relevant information. If, after the review, EPA determined that the MVSL or MBSL was still appropriate, EPA would notify the test sponsors by letter or **Federal Register** notice that they must conduct one of these two tests. If EPA determined that a test was no longer necessary, EPA would notify the test sponsors by letter or **Federal Register** notice that further testing was not triggered. EPA's rationale in allowing test sponsors to use either the MVSL or MBSL test is described in a final rule published in the **Federal Register** of April 5, 1990 (55 FR 12639).

Previous test rules (mesityl oxide, 50 FR 51857, December 20, 1985; and C9 aromatic hydrocarbon, 50 FR 20622, May 17, 1985, are examples) have included a requirement that certain test results (positive for testing based on preliminary hazard data; positive or equivocal for testing based on production volume) in one or more of the following mutagenicity assays resulted in a requirement for chronic oncogenicity bioassay testing: (1) The gene mutation assay in mammalian cells in culture; (2) the sex-linked recessive

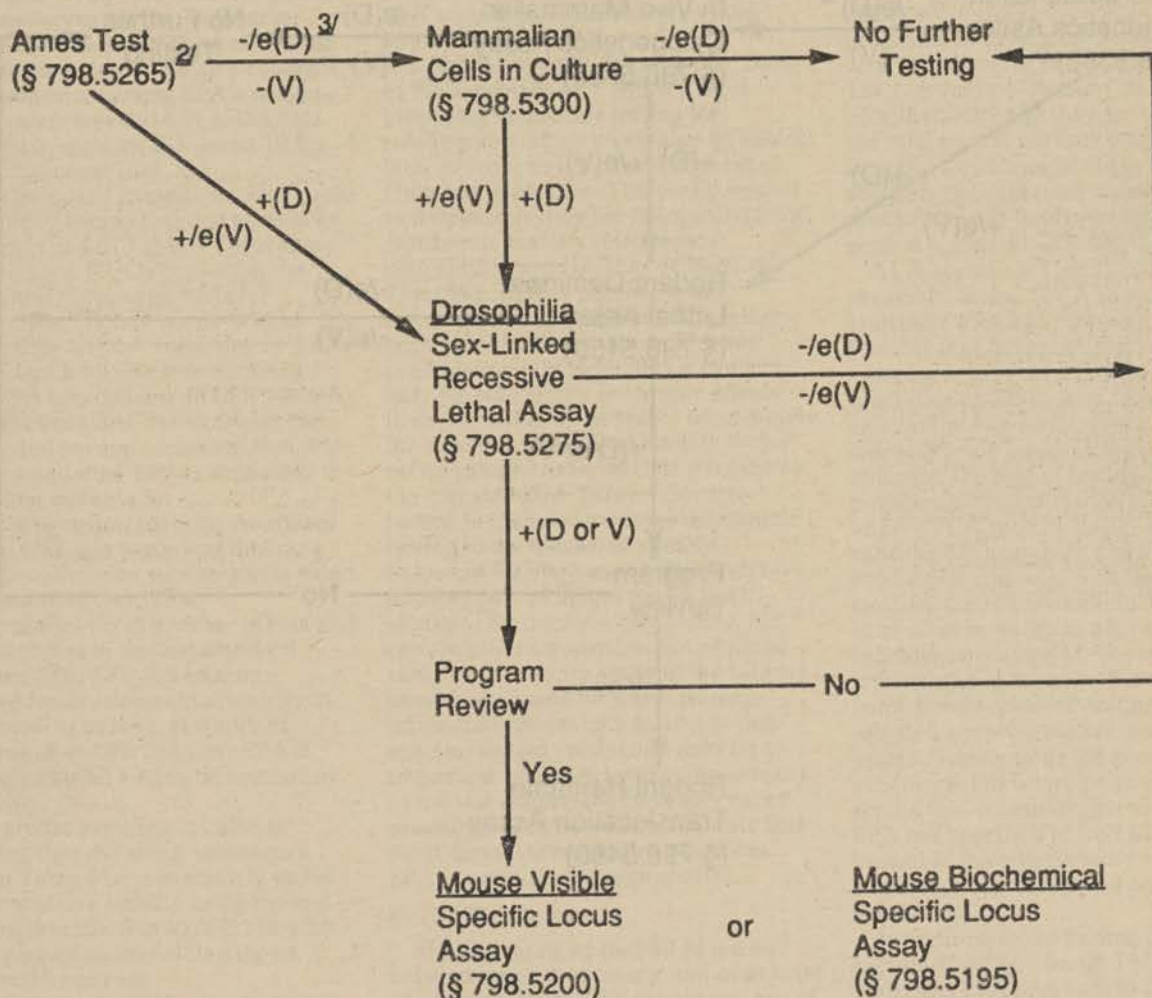
lethal gene mutation assay in *Drosophila melanogaster*; (3) the *in vitro* cytogenetics assay in mammalian cells; and (4) the *in vivo* mammalian cytogenetics assay. However, owing to the complex nature of this category test rule and certain economic considerations, for the purposes of this test rule only, EPA is not proposing to trigger oncogenicity testing from mutagenicity test results. Rather, EPA is proposing that glycidol or a representative member of any subcategory be tested for oncogenicity whenever the annual production volume of the substance or the annual aggregate production volume of the subcategory reaches or exceeds 10 million pounds. EPA's proposed TSCA section 8(a) rule for monitoring production volume and proposed mechanism for notifying manufacturers that testing must be initiated are discussed in Unit III.G. of this preamble.

The test batteries for mutagenicity which EPA is proposing for selected members of this chemical category are depicted in the following charts:

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# CHART 1 -- MUTAGENICITY TESTING SEQUENCE FOR GENE MUTATION<sup>1/</sup>



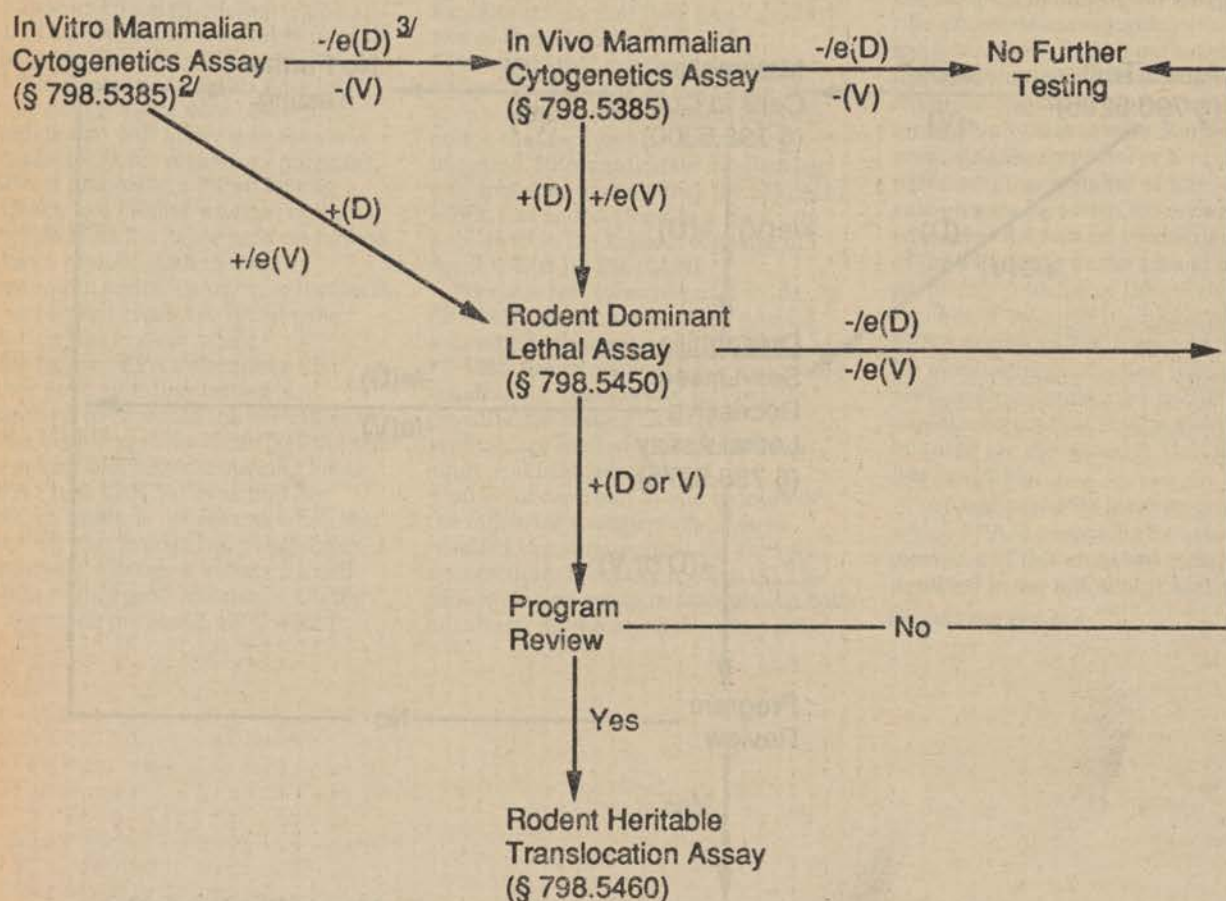
<sup>1/</sup> This scheme applies to representative test substances for subcategories for which testing has been proposed based on available hazard information or for subcategories having annual aggregate production volumes of 10 million pounds or greater. Representative test substances for subcategories having aggregate annual production volumes of 1 million pounds or greater, but less than 10 million pounds, are proposed to be tested only in the Ames Test and Mammalian Cells in Culture test, with no triggering to further mutagenicity testing. If the subcategories subject to this proposed limited testing later attain annual aggregate production volumes of 10 million pounds or greater, then representative members are subject to the entire testing sequence.

<sup>2/</sup> 40 CFR citation for the appropriate TSCA Health Effects Testing Guideline which is proposed as the test standard.

<sup>3/</sup> Indicates result (+ is positive; e is equivocal; and - is negative) required for substances being tested because of preliminary hazard data on the subcategories (D), or because the subcategory annual aggregate production volume testing trigger (10 million pounds or greater) has been met (V).



## CHART 2 -- MUTAGENICITY TESTING SEQUENCE FOR CHROMOSOMAL ABERRATION <sup>1/</sup>



<sup>1/</sup> This scheme applies to representative test substances for subcategories for which testing has been proposed based on available hazard information or for subcategories having annual aggregate production volumes of 10 million pounds or greater. Representative test substances for subcategories having annual production volumes of 1 million pounds or greater, but less than 10 million pounds, are proposed to be tested only in the In Vitro and In Vivo Mammalian Cytogenetics assay, with no triggering to further mutagenicity or oncogenicity testing. If the subcategories subject to this proposed limited testing later attain annual aggregate production volumes of 10 million pounds or greater, then representative members are subject to the entire testing sequence.

<sup>2/</sup> 40 CFR citation for the appropriate TSCA Health Effects Testing Guideline which is proposed as the test standard.

<sup>3/</sup> Indicates result (+ is positive; e is equivocal; and - is negative) required for substances being tested because of preliminary hazard data on the subcategories (D), or because the subcategory annual aggregate production volume testing trigger (10 million pounds or greater) has been met (V).



EPA is proposing that glycidol and the selected representative members of the subcategories listed in Table 5 shall be tested in both the tiered sequences of tests for gene mutation and chromosomal aberration described in this Unit. EPA has proposed the specific mutagenicity assays that will serve, except as noted, as the entry points for each substance into these two complete testing sequences, using EPA's weight-of-the-evidence evaluation of the data contained in sections II.1. and 2. of the support document (Ref. 3).

EPA's proposed immediately-required mutagenicity testing and test standards are summarized in Table 5. For whole-animal assays, EPA is proposing the species, and the gavage route for exposure. For the one whole-animal mutagenicity test not appearing in Table 5, the rodent heritable translocation assay, EPA is proposing 40 CFR 798.5460 as the test standard, the mouse as the species, and gavage administration. For the *in vitro* studies, EPA is proposing the test system in Table 5.

3. *Developmental toxicity.* As shown in Table 4, EPA is proposing that nine members of the nine subcategories listed be immediately tested for developmental toxicity either in rats and mice according to the test standard described in 40 CFR 798.4900 or screened for developmental toxicity in rats according to the test standard described in 40 CFR 798.4420. EPA is proposing that all testing be conducted by gavage.

4. *Reproductive toxicity.* EPA is proposing that the seven substances listed in Table 4 be immediately tested for reproductive toxicity using the test standard described in 40 CFR 798.4700. EPA is proposing that all testing be performed by gavage.

5. *Neurotoxicity.* EPA is proposing that the 12 substances listed in Table 4 be immediately tested in oral (gavage) neurotoxicity studies in the rat. The tests to be performed and the proposed test standards are the following: (a) An acute and subchronic functional observational battery (40 CFR 798.6050); (b) an acute and subchronic motor activity test (40 CFR 798.6200); and a subchronic neuropathology test (40 CFR 798.6400). The subchronic neurotoxicity tests could be combined with the oral toxicity test, provided all test guideline criteria are followed, using 10 animals for each dose per sex.

As noted in Table 4, in some cases only subchronic neurotoxicity studies are proposed. To minimize and distribute testing costs while ensuring adequate testing, EPA is proposing to require subchronic neurotoxicity testing whenever neurotoxicity testing is

appropriate, but to require acute neurotoxicity testing only when there are preliminary hazard data indicating a concern for neurotoxicity or when the subcategory testing has been triggered by an annual subcategory production volume of 10 million pounds or greater. EPA solicits public comment on this approach.

6. *Subchronic (90-day) toxicity.* Many of the substances for which EPA is proposing immediate testing for subchronic toxicity could also be subject later to proposed oncogenicity testing. Only one substance is currently subject to proposed testing for oncogenicity and subchronic toxicity (bisphenol A diglycidyl ether; CAS No. 1675-54-3). Therefore, EPA is proposing that bisphenol A diglycidyl ether, together with substances for which EPA has preliminary data indicating a concern only for subchronic or chronic effects (listed in Table 4), be tested immediately for subchronic (90-day) toxicity in the rat by gavage, using 40 CFR 798.2650 as the test standard. This subchronic testing in the rat, as well as subchronic testing in the mouse, is already proposed for bisphenol A diglycidyl ether as part of the proposed test standard for oncogenicity testing. For certain other substances, the required subchronic toxicity study in the rat may provide the basis for setting dosage levels for oncogenicity testing in this species, should production data later trigger oncogenicity testing. Since many of the test substances have low vapor pressures, are known skin irritants and elicit dermal sensitization reactions, EPA is proposing gavage studies.

#### C. Test Substances

EPA is proposing that all of the test substances be monomeric and of at least 99-percent purity. The concentrations of suspected impurities contained in the test substances, such as epichlorohydrin, would be determined and reported. EPA is specifying relatively pure monomeric substances for testing because EPA is interested in evaluating the effects attributable to these substances themselves.

#### D. Persons Required to Test

EPA is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process, any glycidyl on, or added to, the public or confidential portions of the TSCA section 8(b) Inventory, at any time from the effective date of the final test rule to the end of the reimbursement period, be subject to the testing proposed by this rule. Those who manufacture or import glycidyls as byproducts are considered manufacturers under this rule.

TSCA section 5(b) requires that manufacturers of any new glycidyl, as defined in Unit III.C.1. of this preamble, comply with a TSCA section 4(a) test rule on that substance prior to submitting a premanufacture notice (PMN) for the new substance under TSCA section 5(a). However, EPA is proposing to defer such compliance until after the chemical is reported to the TSCA Inventory. Persons should also note that, although they are subject to the rule, certain persons who manufacture chemicals may be treated similarly to processors under the procedural rule implementing TSCA section 4. (See 40 CFR 790.42.)

As described in Unit IV. of this preamble, under TSCA section 4(a)(1)(B), EPA has proposed making findings that the entire glycidyls category is produced in substantial quantities and that there is or may be substantial human exposure on a category-wide basis. However, to minimize the cost of testing, EPA proposes to trigger testing required under TSCA section 4(a)(1)(B) by subcategory aggregate annual production volumes, with the manufacturers and importers of glycidol or of all substances in a given subcategory paying for the testing of a representative member. For proposed immediately-required testing, EPA has selected a representative member from each subcategory as the proposed test substance. For future proposed production volume-triggered testing, EPA has specified in Unit III.C.3. of this preamble the criteria to be used in selecting a representative test substance.

In addition to the finding under TSCA section 4(a)(1)(B), under TSCA section 4(a)(1)(A) EPA proposes to find that the glycidyls category may present an unreasonable risk of injury to health. However, aside from production volume-triggered testing, when testing is being required because preliminary data indicate that a subcategory may contain members which are oncogenic or mutagenic, EPA intends to require testing of one substance within the subcategory to be paid for by all manufacturers and processors of all substances within the subcategory. For all other health effects, EPA intends to require testing only when preliminary data on a specific substance indicate a concern for a particular health effect, and the costs for the testing would be borne only by the manufacturers and processors of that specific chemical.

1. *Proposed immediately-required testing.* For proposed immediately-required testing, EPA has considered the



following factors in determining who would pay for testing: (a) Whether preliminary hazard data or subcategory annual aggregate production volume, or both, formed the primary basis of concern for proposed testing; (b) the relative ability of the specific test to predict an unreasonable risk of injury to health (for example, a 90-day subchronic toxicity study which investigates multiple health effect endpoints has a greater relative ability to predict injury to health than a test, such as the Ames gene mutation test, which investigates only a single health effect endpoint); (c) the affordability of the testing; and (d) the desirability to minimize, as a matter of policy, the testing burden while, at the same time, ensuring the development of test data adequate for EPA's risk assessment purposes. Proposed immediately-required testing consists of both subcategory-specific and chemical-specific testing based on preliminary data and subcategory-specific testing based on aggregate annual subcategory production volume. Where testing is based on production volume-triggered testing, all manufacturers and processors pay, where subcategory-specific testing is required due to a hazard-based concern for oncogenicity or mutagenicity, all manufacturers and processors pay, and where testing is required based on a chemical-specific hazard concern, only manufacturers and processors of the specific substance(s) pay. However, there are instances in which a test is proposed for a subcategory on the basis of its production volume, but the subcategory also contains one or more members for which the same test requirement is proposed on the basis of preliminary hazard data, presenting a variety of possible test requirement options.

One option would be to require the manufacturers and processors of any substance for which there are preliminary suggestive hazard data to conduct that testing, while selecting another member of the subcategory to be tested to satisfy the subcategory testing triggered by aggregate annual production volume. This approach would increase the total amount of testing, but does not consider the relative ability of the specific test to predict unreasonable risk of injury to health.

Another option would be to select, as the representative test substance to satisfy a proposed subcategory-specific test requirement, one of the subcategory members for which there are preliminary suggestive hazard data, and therefore a chemical-specific test

requirement, for the same endpoint. A criterion, such as the highest production volume among the subcategory members subject to that chemical-specific requirement, could be used to select the test substance to satisfy also the production volume-triggered subcategory-specific requirement for the same test. This approach would decrease the amount of total testing, but does not consider the relative ability of a specific test to determine an unreasonable risk of injury to health. It might also be viewed as inequitable by the manufacturers and processors of the other subcategory members subject to the test on a chemical-specific basis, who would not receive the cost-sharing benefits available to the manufacturers and processors of the representative substance. Other approaches are also possible.

Taking these considerations into account, EPA has selected proposed persons required to test listed in Table 4 of Unit V. of this preamble in the following manner, and requests comment upon this approach: (a) The manufacturers and processors of glycidol are required to test that substance; (b) all manufacturers and processors of all substances in a given subcategory are required to test a representative member whenever mutagenicity or oncogenicity test requirements are based on preliminary adverse hazard data or whenever testing for any effect is triggered by annual subcategory production volume; (c) the manufacturers and processors of a given substance are required to test that substance for effects other than oncogenicity and mutagenicity when the basis for the testing is preliminary hazard data.

When testing proposed for a representative substance of a subcategory is based on subcategory aggregate annual production volume, and there are also preliminary adverse hazard data for one or more substances within the subcategory for the same effect, then the following selection criteria were used:

a. If testing is proposed for a substance based on adverse hazard information and that substance is a member of a subcategory having an annual aggregate production volume of 10 million pounds or greater, then the manufacturers and processors of all substances within the subcategory are required to test. EPA believes that this approach will equitably distribute the relatively greater testing costs incurred by such subcategories.

b. For subchronic toxicity testing, which has a somewhat greater relative

ability than many other single tests to determine unreasonable risk of injury to health, for subcategories having annual aggregate production volumes of at least 1 million but less than 10 million pounds, manufacturers and processors of specific substances in a given subcategory for which proposed chemical-specific testing is based on adverse preliminary hazard data are required to test the specific substances; manufacturers and processors of all of the substances within the subcategory would be required to test a different representative test substance to satisfy the subcategory production volume-triggered testing requirement.

c. For neurotoxicity testing, for subcategories having annual aggregate production volumes of at least 1 million but less than 10 million pounds (triggering a subcategory requirement for subchronic neurotoxicity testing only) which also contain one or more members subject to both acute and subchronic neurotoxicity testing because of preliminary hazard data for acute and subchronic neurotoxicity, those members would be selected as the representative test substances to satisfy subcategory volume-triggered testing requirements for subchronic neurotoxicity. The subchronic testing would be paid for by all manufacturers and importers of all substances in the given subcategory. However, because acute testing would not be automatically required until a subcategory's annual aggregate production volume reached or exceeded 10 million pounds, the manufacturers and processors of those representative test substances would be required to conduct the additional acute neurotoxicity testing based on preliminary hazard data demonstrating potential acute neurotoxicity.

2. *Future production volume-triggered testing.* For future production volume-triggered testing for glycidol or for subcategories under TSCA section 4(a)(1)(B), all manufacturers and processors of glycidol or of each substance in the subcategory would be required to test a representative test substance. EPA believes that this proposed selection of persons required to test will equitably distribute the testing burden while ensuring the development of test data adequate for risk assessment purposes. EPA requests public comment on this approach.

3. *General testing considerations.* Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers



or processors who are subject to this rule to designate one person or a qualified third person to conduct the tests and submit data on their behalf. TSCA section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to test or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR part 790.

Processors subject to this rule, unless they are also manufacturers, are not required to submit letters of intent or exemption applications, or to conduct testing unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. EPA expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted conditional exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, EPA will publish a separate notice in the *Federal Register* to notify processors to respond; this procedure is described in 40 CFR part 790.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing of certain substances subject to this test rule. EPA is interested in evaluating the effects attributable to these substances themselves, and therefore, has specified relatively pure substances for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR part 790 for single-phase rulemaking.

#### E. Reporting Requirements

1. Under TSCA section 4, EPA is proposing that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice Standards (GLPS), which appear in 40 CFR part 792.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. EPA is proposing specific reporting requirements for each of the proposed test standards as presented in Tables 2 and 3 of Unit V.A. of this preamble and

in the sample regulatory language contained in this preamble.

As presented in Tables 2 and 3 of Unit V.A., the proposed reporting requirements for testing triggered by TSCA section 8(a) reports are calculated from the date of notification by EPA of manufacturers/importers of glycidol or of all substances in a given subcategory that testing should be initiated, with two exceptions. For the MVSL or MBSL and the heritable translocation cytogenetics test in the mouse, the proposed reporting requirements are calculated from the date of EPA's notification of manufacturers/importers that such testing should be initiated.

For immediately required testing proposed in Unit V.B. of this preamble, the time periods allowed for the proposed reporting requirements are the same as those presented in Tables 2 and 3 of Unit V.A. of this preamble, except that these requirements are calculated from the effective date of the final rule, with two exceptions. Proposed reporting requirements for the MVSL or MBSL gene mutation test and the heritable translocation cytogenetics test in the mouse are calculated from the date of EPA's notification of the test sponsor(s) that such testing should be initiated.

TSCA section 14(b) governs EPA's disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, EPA will publish a notice of receipt in the *Federal Register* as required by section 4(d) of TSCA.

Persons who export a chemical substance or mixture which is subject to a final TSCA section 4 rule are subject to the export reporting requirements of section 12(b) of TSCA. Regulations implementing TSCA section 12(b) are found in 40 CFR part 707. To fulfill the annual export notification requirement and for the purposes of this rule only, EPA proposes to require persons to submit one notice per country for the first manufacture of any member of the category of glycidyls.

2. Under TSCA section 8, EPA is proposing that any person who manufactures or imports any of the chemical substances currently comprising the chemical category of glycidyls (publicly identified members of which are listed in Unit III.C.1. of this preamble), or any chemical substance falling within the definition of this chemical category which has subsequently been entered into either the public or confidential portion of the TSCA Chemical Substance Inventory, as of the effective date of the final test rule for this chemical category would submit a report to EPA within 60 days after the conclusion of their corporate fiscal year

in which the person manufactured or imported any of these substances.

Any person who manufactures or imports any of these chemical substances in a year following that for which an initial report was submitted would be required to submit a new report within 60 days of the conclusion of that corporate fiscal year.

The report would contain the following information:

- (a) Company name and address.
- (b) Name, address, and telephone number of the principal technical contact.
- (c) The identity and Chemical Abstracts Service registry number (CAS number) of each substance manufactured or imported.

- (d) The quantity (by weight) of each substance manufactured or imported during the latest corporate fiscal year.

If this report is submitted within the year preceding the start of a reporting period under the Inventory Update Rule, the submitter would not be required to report the same information again for that reporting period. The details of this exemption are set forth in 40 CFR 710.35.

#### F. Tentative Regulatory Language

Because this rule is novel in many ways, EPA is not proposing complete rule language at this time. EPA believes that the tests and reporting requirements proposed are adequately presented in this preamble for comment. EPA recognizes, however, that there may be certain aspects of the proposal that are not included in the sample regulatory text. For example, EPA's proposal to review "new" data that did not exist until after the effective date of the final rule prior to notification of persons that they are required to test is currently described in the preamble. If adopted, it would be added to the regulatory text of the final rule.

1. The following is representative proposed language for reporting requirements:

##### § 704.xx Glycidol and its derivatives.

(a) *Substances for which reporting is required.* The chemical substances for which reporting is required under this rule consist of glycidol and its ethers and esters, as defined in § 799.xxxx of this chapter, which are currently listed on, or added to, the public or confidential portions of the TSCA Inventory of Chemical Substances maintained by EPA under TSCA section 8(b) at any time after (the effective date of the final rule). New chemical substances meeting this definition shall also be subject to this section once



entered into the TSCA Inventory of Chemical Substances.

(b) *Persons who must report.* The following persons, unless exempt as provided in § 704.5 of this chapter, are subject to the reporting requirements of this rule; a person may be required to report more than once in response to this rule.

(1) *Initial reporting.* Persons who manufacture or import any substance identified in paragraph (a) of this section for commercial purposes during the person's latest complete corporate fiscal year prior to (the effective date of the final rule) are required to report.

(2) *Subsequent reporting.* Persons who manufacture or import any substance identified in paragraph (a) of this section for commercial purposes after (the effective date of the final rule) are required to report. The persons described in this paragraph (b)(2) include persons who report initially in response to paragraph (b)(1) of this section and persons who commence the manufacture or importation of any substance identified in paragraph (a) of this section after (the effective date of the final rule).

(c) *When to report—(1) Initial reporting.* Persons described in paragraph (b)(1) of this section must submit an initial report within 60 days of (the effective date of the final rule).

(2) *Subsequent reporting.* Persons described in paragraph (b)(2) of this section must submit a report within 60 days of the completion of each corporate fiscal year during which they manufacture or import any substance identified in paragraph (a) of this section. Persons shall submit a separate report for each corporate fiscal year in which they are subject to this section.

(3) *Duplicative reporting.* Persons reporting under this section are exempt, pursuant to 40 CFR 710.35, from duplicative reporting for the Inventory Update rule.

(d) *What information to report.* All persons subject to this section shall report the following information to EPA:

(1) Company name and headquarters address.

(2) Name, address, and telephone number (including area code) of the company's principal technical contact.

(3) The chemical name and Chemical Abstracts Service Registry Number (CAS number) of each chemical substance identified in paragraph (a) manufactured or imported during the latest complete corporate fiscal year.

(4) The quantity (in pounds) of each such substance manufactured or imported during the latest complete corporate fiscal year.

(e) *Where to send reports.* Reports must be submitted by certified mail to the United States Environmental Protection Agency, OTS Document Receipt Office, 401 M St., SW., Washington, DC 20460, Attn: Glycidol and its derivatives.

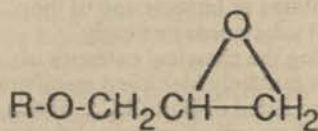
2. The following is representative proposed language for the test rule for these chemical substances. Upon final promulgation, the test rule will be added to part 799, subpart B.

§ 799.xxxx Glycidol and its derivatives.

(a) *Scope and Purpose.* This section requires persons who manufacture, import, or process members of the chemical category glycidol and its derivatives ("glycidyls") to conduct health effects testing. The type of testing required depends in part upon the aggregate annual production volume of the subcategory of which a particular chemical substance is a member. When the annual production volume of a particular subcategory reaches 10 million pounds, persons who manufacture, import, or process members of the subcategory will be responsible for conducting comprehensive testing of a representative member of the subcategory. When the aggregate annual production volume of a particular subcategory reaches 1 million pounds but is less than 10 million pounds, persons who manufacture, import, or process members of the subcategory will be responsible for conducting screening testing of a representative member of the subcategory. Further, this section specifies additional health effects testing for certain members of the category of glycidyls as specified in this section.

(b) *Definitions.* The definitions in section 3 of TSCA and the definitions of § 790.3 of this chapter also apply to this section.

(1) *Glycidol and its derivatives*, also referred to as "glycidyls," refers to chemical substances of the general formula:



Where R is a hydrogen atom or any alkyl, aryl, or acyl group. R is unrestricted as to the number and type of substituents it may carry.

(2) *Comprehensive subcategory testing* refers to testing of one chemical substance within a chemical

subcategory whose aggregate annual production equals or exceeds 10 million pounds. The testing to be conducted is testing according to the following guidelines included in part 798 of this chapter, with certain modifications as included in paragraph (g) of this section:

(i) Oncogenicity, § 798.3300 and 798.2650.

(ii) Developmental Toxicity, § 798.4900.

(iii) Reproductive Toxicity, § 798.4700.

(iv) Acute Neurotoxicity, §§ 798.6050 and 798.6200.

(v) Subchronic neurotoxicity, § 798.6050, 798.6200, 798.6400.

(vi) Mutagenicity § 798.5265, 798.5300, 798.5275, 798.5200 or 798.5195, 798.5375, 798.5385, 798.5450, 798.5460.

(3) *Screening subcategory testing* refers to testing of one chemical substance within a chemical category whose aggregate annual production equals or exceeds 1 million pounds but is less than 10 million pounds. The testing to be conducted is testing according to the following guidelines included in part 798 of this chapter, with certain modifications as included in paragraph (h) of this section:

(i) Subchronic toxicity § 798.2650.

(ii) Developmental toxicity screen § 798.4420.

(iii) Mutagenicity screen §§ 798.5265, 798.5300, 798.5375, 798.5385.

(iv) Subchronic neurotoxicity screen § 798.6050, 798.6400, 798.6200.

(4) *Health effect-specific subcategory testing* refers to mutagenicity testing of one chemical substance, within a chemical subcategory having an annual aggregate production volume of less than 10 million pounds, for which testing is based on preliminary hazard information. The mutagenicity testing to be conducted is testing according to the following guidelines included in part 798 of this chapter, with certain modifications as included in paragraph (i) of this section:

(i) Mutagenicity §§ 798.5265, 798.5300, 798.5275, 798.5200 or 798.5195, 798.5375, 798.5385, 798.5450, and 798.5460.

(ii) [Reserved]

(5) *Health effect-specific testing for specific substances* refers to testing of specific chemical substances for neurotoxicity, reproductive and fertility effects, or subchronic toxicity. The testing to be conducted is testing according to the following guidelines included in part 798 of this chapter, with certain modifications as included in paragraph (j) of this section:

(i) Acute neurotoxicity §§ 798.6050 and 798.6200.

(ii) Subchronic neurotoxicity §§ 798.6050, 798.6200, 798.6400.



(iii) Reproductive toxicity § 798.4700.

(iv) Subchronic toxicity § 798.2650.

(c) *Chemical substances subject to testing.* (1) This section applies to any chemical substance within the category "glycidol and its derivatives." The chemical substances in this category listed on the TSCA section 8(b) public inventory are identified in this paragraph. (Glycidol and a list of all other substances meeting the definitions of the substances contained in the 21 subcategories of its derivatives at the time of this proposed rule are identified in a table in Unit III.C.1. of this preamble. For the final test rule, the list will be included in the codified text).

(2) This section also applies to any new chemical substance within the category of "glycidol and its derivatives." However, persons subject to this section by virtue of their intention to manufacture or import a new chemical substance in the category of "glycidol and its derivatives" are not required to comply with this section prior to submitting a premanufacture notification (PMN) under TSCA section 5(a) for such substance. However, they must comply with this section once the substance is added to the TSCA section 8(b) Inventory.

(d) *Persons required to submit study plans, conduct tests, and submit data—*

(1) *Production volume-triggered testing.* (i) *Comprehensive subcategory testing.* (A) Except as provided in paragraph (c)(2) of this section, all persons who manufacture (including import) or process or intend to manufacture or process glycidol, or any member or any combination of members of a subcategory of the category glycidol and its derivatives as listed in paragraph (c) of this section that attains an annual aggregate production volume of at least 10 million pounds, as described in paragraph (d)(1)(i)(B) of this section or as determined by EPA pursuant to paragraph (d)(1)(iii) of this section from TSCA section 8(a) reports submitted pursuant to § 704.XX of this chapter, from the effective date of this section to the end of the reimbursement period, shall submit letters of intent to test, submit study plans, conduct tests,

and submit data, or submit exemption applications, as described in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking.

(B) EPA has determined that Subcategory VI-A as identified in paragraph (c) of this section has met the annual aggregate production volume trigger of 10 million pounds and is therefore subject to comprehensive subcategory testing in accordance with this section.

(ii) *Screening subcategory testing.* (A) All persons who manufacture (including import) or process or intend to manufacture or process glycidol, or any member or any combination of members of a subcategory of the category glycidol and its derivatives as listed in paragraph (c) of this section that attains an annual aggregate production volume of at least 1 million pounds, but less than 10 million pounds, as described in paragraph (d)(1)(ii)(B) or as determined by EPA pursuant to paragraph (d)(1)(iii) of this section from TSCA section 8(a) reports submitted pursuant to § 704.XX of this chapter, from the effective date of this section to the end of the reimbursement period, shall submit letters of intent to test, submit study plans, conduct tests, and submit data, or submit exemption applications, as described in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking.

(B) EPA has determined that Subcategories I-A, I-C, II-A, III-A, IV-A, V-B, VII-A, and VII-B as identified in paragraph (c) of this section have met the annual aggregate production volume trigger of 1 million pounds, but less than 10 million pounds, and are therefore subject to screening subcategory testing in accordance with this section.

(iii) *Future testing.* (A) EPA will notify all persons required to conduct testing pursuant to paragraphs (d)(1)(i) and (d)(1)(ii) of this section by certified letter or Federal Register notice that the annual production volume of glycidol or a specific subcategory has reached either 1 or 10 million pounds, as applicable, and that testing shall be initiated pursuant to this section using

an EPA-specified representative test substance.

(B) Subcategories of glycidol derivatives that become subject to this section under this paragraph shall be added to paragraph (d)(1)(i)(B) or (d)(1)(ii)(B) and paragraphs (e) and (f) of this section on a yearly basis by Federal Register notice.

(C) Persons who manufacture, import, or process these substances only as an impurity are not subject to these requirements.

(2) *Health effect-specific subcategory mutagenicity testing.* (i) Except as provided in paragraph (c)(2) of this section, all persons who manufacture (including import) or process or intend to manufacture or process any member, or any combination of members of the following subcategories of the category glycidol and its derivatives as identified in paragraph (c) of this section, from the effective date of this section to the end of the reimbursement period, shall submit letters of intent to test, submit study plans, conduct tests, and submit data, or submit exemption applications, as described in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking: glycidol and Subcategories I-A, I-C, I-D, II-A, III-A, IV-A, V-A, VI-A, VI-C, VII-B, and VII-C.

(ii) Persons who manufacture, import, or process these substances only as an impurity are not subject to these requirements.

(3) *Health effect-specific testing for specific substances.* (i) All persons who manufacture (including import) or process or intend to manufacture or process glycidol or any of the following members of the category glycidol and its derivatives, from the effective date of this section to the end of the reimbursement period, shall submit letters of intent to test, submit study plans, conduct tests, and submit data, or submit exemption applications, as described in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking. The substances for which persons are subject to testing under this paragraph are as follows:

TABLE 1.—SUBSTANCES SUBJECT TO HEALTH EFFECTS TESTING

Testing Endpoint	Chemical Substance	CAS No.
Subchronic Toxicity.....	n-butyl glycidyl ether	2426-08-6
	alkyl (C <sub>8</sub> -C <sub>18</sub> ) glycidyl ether	68609-96-1
	1,4-butanediol diglycidyl ether	2425-79-8
	alkyl (C <sub>10</sub> -C <sub>18</sub> ) glycidyl ether	68081-84-5
	glycidyl methacrylate	106-91-2
	neopentyl glycol diglycidyl ether	17557-23-2
Neurotoxicity.....	glycidol	556-52-5
	n-butyl glycidyl ether	2426-08-6



TABLE 1.—SUBSTANCES SUBJECT TO HEALTH EFFECTS TESTING—Continued

Testing Endpoint	Chemical Substance	CAS No.
Reproductive and Fertility Effects.....	allyl glycidyl ether	106-92-3
	3-(trimethoxysilyl)propyl glycidyl ether	2530-83-8
	phenyl glycidyl ether	122-60-1
	o-cresyl glycidyl ether	2210-79-9
	1,4-butanediol diglycidyl ether	2425-79-8
	glycidol	556-52-5
	n-butyl glycidyl ether	2426-08-6
	alkyl (C <sub>6</sub> -C <sub>10</sub> ) glycidyl ether,	68609-96-1
	allyl glycidyl ether	106-92-3
	3-(trimethoxysilyl)propyl glycidyl ether	2530-83-8
	phenyl glycidyl ether	122-60-1

(ii) Persons who manufacture, import, or process these substances only as an impurity are not subject to these requirements.

(e) *Test substances*—(1) *Comprehensive subcategory testing.* The following representative test substances, identified by chemical name, Chemical Abstracts Service Registry Number

(CAS No.), and subcategory, as identified in paragraph (c) of this section, shall be tested in accordance with this section:

TABLE 2.—SUBSTANCES SUBJECT TO COMPREHENSIVE SUBCATEGORY TESTING

Test Substance	CAS No.	Sub-category
Bisphenol A diglycidyl ether.....	1675-54-3	VI-A

(2) *Screening subcategory testing.* The following representative test substances, identified by chemical name, Chemical Abstracts Service Registry Number (CAS No.), and subcategory, as identified in paragraph (c) of this section, shall be tested in accordance with this section:

TABLE 3.—SUBSTANCES SUBJECT TO SCREENING SUBCATEGORY TESTING

Test Substance	CAS No.	Sub-category
n-butyl glycidyl ether.....	2426-08-6	I-A
tert-butyl glycidyl ether.....	7665-72-7	I-A
allyl glycidyl ether.....	106-92-3	I-C
alkyl (C <sub>12</sub> -C <sub>14</sub> ) glycidyl ether.....	68609-97-2	II-A
3-(trimethoxysilyl) propyl glycidyl ether.....	2530-83-8	III-A
o-cresyl glycidyl ether.....	2210-79-9	IV-A
phenyl glycidyl ether.....	122-60-1	IV-A
1,2,3-propanetriyl ester of 12- (oxiranylmethoxy)- 9-octadecenoic acid.....	74398-71-3	V-B
glycidyl ester of neodecanoic acid.....	26761-45-5	VII-A
glycidyl methacrylate.....	106-91-2	VII-B
glycidyl acrylate.....	106-90-1	VII-B

(3) *Selection criteria used by EPA for selection of representative test substances for testing shared by all manufacturers, importers, and processors of a subcategory*—(i) *Mutagenicity and oncogenicity.* For mutagenicity and oncogenicity testing triggered by future production volume, EPA will consider mutagenicity and oncogenicity test data on subcategory members and structural analogues, in addition to production volume and

exposure data, in selecting the test substance.

(ii) *Other health effects.* For subcategory testing for all health effects other than mutagenicity and oncogenicity triggered by future production volume, EPA will determine from TSCA section 8(a) reports submitted pursuant to § 704.XX of this chapter the substance having the largest production (including importation) volume and specify that subcategory member as the representative test

substance, unless available exposure information indicates that a different substance has a higher human exposure potential.

(4) *Health effect-specific subcategory mutagenicity testing.* The following representative substances, identified by chemical name, Chemical Abstracts Service Registry Number (CAS. No.), and subcategory, as identified in paragraph (c) of this section, shall be tested in accordance with this section:



TABLE 4.—SUBSTANCES SUBJECT TO MUTAGENICITY TESTING

Test Substance	CAS No.	Sub-category
glycidol.....	556-52-5	None
<i>n</i> -butyl glycidyl ether.....	2426-08-6	I-A
allyl glycidyl ether.....	106-92-3	I-C
2-ethylhexyl glycidyl ether.....	2461-15-6	I-D
alkyl (C <sub>12</sub> -C <sub>14</sub> ) glycidyl ether.....	68609-97-2	II-A
3-(trimethoxysilyl) propyl glycidyl ether.....	2530-83-8	III-A
<i>o</i> -cresyl glycidyl ether.....	2210-79-9	IV-A
1,4-butanediol diglycidyl ether.....	2425-79-8	V-A
4-(diglycidylamino)phenyl glycidyl ether.....	5026-74-4	VI-C
glycidyl acrylate.....	106-90-1	VII-B
diglycidyl ester of hexahydrophthalic acid.....	5493-45-8	VII-C

(5) *Purity of the representative test substances.* All test substances shall be of at least 99 percent purity and exhibit a molecular weight that indicates a monomeric state.

(f) *Required testing—(1) Comprehensive subcategory testing (annual aggregate subcategory production volume equal to or greater than 10 million pounds).* (i) The representative test substance in subcategory VI-A, identified in paragraph (e)(1) of this section, shall be tested for oncogenicity, subchronic toxicity, acute and subchronic neurotoxicity, developmental toxicity, reproductive toxicity and mutagenicity, pursuant to paragraph (g) of this section.

(iii) [Reserved]

(2) *Screening subcategory testing (annual aggregate subcategory production volume equal to or greater than 1 million pounds, but less than 10 million pounds).* (i) The first representative test substance in subcategory I-A, identified as *n*-butyl glycidyl ether in paragraph (e)(2) of this section, shall be tested for subchronic neurotoxicity and developmental toxicity pursuant to paragraph (h) of this section. The second representative test substance in subcategory I-A, identified as *tert*-butyl glycidyl ether in paragraph (e)(2) of this section, shall be tested for subchronic toxicity pursuant to paragraph (h) of this section.

(ii) The representative test substance in subcategory I-C, identified in paragraph (e)(2) of this section, shall be tested for subchronic toxicity, subchronic neurotoxicity, and developmental toxicity pursuant to paragraph (h) of this section.

(iii) The representative test substance in subcategory II-A, identified in paragraph (e)(2) of this section, shall be

tested for subchronic toxicity, subchronic neurotoxicity, and developmental toxicity pursuant to paragraph (h) of this section.

(iv) The representative test substance in subcategory III-A, identified in paragraph (e)(2) of this section, shall be tested for subchronic toxicity, subchronic neurotoxicity, and developmental toxicity pursuant to paragraph (h) of this section.

(v) The first representative test substance in subcategory IV-A, identified as *o*-cresyl glycidyl ether in paragraph (e)(2) of this section, shall be tested for subchronic toxicity, subchronic neurotoxicity, and developmental toxicity, pursuant to paragraph (h) of this section. The second representative test substance in subcategory IV-A, identified as phenyl glycidyl ether in paragraph (e)(2) of this section, shall be tested for subchronic neurotoxicity, pursuant to paragraph (h) of this section.

(vi) The representative test substance in subcategory V-B, identified in paragraph (e)(2) of this section, shall be tested for subchronic toxicity, subchronic neurotoxicity, developmental toxicity, and mutagenicity pursuant to paragraph (h) of this section.

(vii) The representative test substance in subcategory VII-A, identified in paragraph (e)(2) of this section, shall be tested for subchronic toxicity, subchronic neurotoxicity, developmental toxicity, and mutagenicity pursuant to paragraph (h) of this section.

(viii) Reserved.

(ix) The first representative test substance in subcategory VII-B, identified as glycidyl methacrylate in paragraph (e)(2) of this section, shall be tested for subchronic neurotoxicity and developmental toxicity pursuant to

paragraph (h) of this section. The second representative test substance in subcategory VII-B, identified as glycidyl acrylate in paragraph (e)(2) of this section, shall be tested for subchronic toxicity pursuant to paragraph (h) of this section.

(3) *Health effects-specific testing—(i) Mutagenicity.* (A) Glycidol [CAS No. 556-52-5] shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B), (i)(1)(i)(C), (i)(2)(i)(A), and (i)(2)(i)(B) of this section shall not apply.

(B) The representative test substance in subcategory I-A, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B), (i)(2)(i)(A), and (i)(2)(i)(B) of this section shall not apply.

(C) The representative test substance in subcategory I-C, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B), (i)(1)(i)(C), (i)(2)(i)(A), and (i)(2)(i)(B) of this section shall not apply.

(D) The representative test substance in subcategory I-D, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraph (i)(1)(i)(A) of this section shall not apply.

(E) The representative test substance in subcategory II-A, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(2)(i)(C) and (i)(2)(i)(D) of this section shall not apply.



(F) The representative test substance in subcategory III-A, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B) of this section shall not apply.

(G) The representative test substance in subcategory IV-A, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B), and (i)(2)(i) of this section shall not apply.

(H) The representative test substance in subcategory V-A, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B), (i)(1)(i)(C), (i)(2)(i)(A), and (i)(2)(i)(B) of this section shall not apply.

(I) The representative test substance in subcategory VI-C, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B), (i)(1)(i)(C), (i)(2)(i)(A), and (i)(2)(i)(B) shall not apply.

(J) The representative test substance in subcategory VII-B, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B), (i)(2)(i)(A), and (i)(2)(i)(B) of this section shall not apply.

(K) The representative test substance in subcategory VII-C, identified in paragraph (e)(4) of this section, shall be tested for mutagenicity according to paragraph (i) of this section except that paragraphs (i)(1)(i)(A), (i)(1)(i)(B), (i)(2)(i)(A), and (i)(2)(i)(B) of this section shall not apply.

(ii) *Subchronic toxicity.* The chemical substances identified in paragraph (d)(3)(i) of this section shall be tested for subchronic toxicity in accordance with paragraph (j) of this section.

(iii) *Reproductive and fertility effects.* The chemical substances identified in paragraph (d)(3)(i) of this section shall be tested for reproductive and fertility effects in accordance with paragraph (j) of this section.

(iv) *Neurotoxic effects.* (A) Glycidol (CAS No. 556-52-5) shall be tested for neurotoxic effects according to paragraph (j) of this section.

(B) *n*-Butyl glycidyl ether (CAS No. 2426-08-6) shall be tested for neurotoxic effects according to paragraph (k) of this section except for the subchronic testing pursuant to paragraphs (j)(3)(i)(A), (j)(3)(i)(B), and (j)(3)(i)(C) of this section.

(C) Allyl glycidyl ether (CAS No. 106-92-3) shall be tested for neurotoxic

effects according to paragraph (j) of this section, except for the subchronic testing pursuant to paragraphs (j)(3)(i)(A), (j)(3)(i)(B), and (j)(3)(i)(C) of this section.

(D) 3-(Trimethoxysilyl)propyl glycidyl ether (CAS No. 2530-83-8) shall be tested for neurotoxic effects according to paragraph (j) of this section except for the subchronic testing pursuant to paragraphs (j)(3)(i)(A), (j)(3)(i)(B), and (j)(3)(i)(C) of this section.

(E) Phenyl glycidyl ether (CAS No. 122-60-1) shall be tested for neurotoxic effects according to paragraph (j) of this section except for the subchronic testing pursuant to paragraphs (j)(3)(i)(A), (j)(3)(i)(B), and (j)(3)(i)(C) of this section.

(F) *o*-Cresyl glycidyl ether (CAS No. 2210-79-9) shall be tested for neurotoxic effects according to paragraph (j) of this section except for the subchronic testing pursuant to paragraphs (j)(3)(i)(A), (j)(3)(i)(B), and (j)(3)(i)(C) of this section.

(G) 1,4-Butanediol diglycidyl ether (CAS No. 2425-79-8) shall be tested for neurotoxic effects according to paragraph (j) of this section.

(g) *Test standards and reporting requirements for comprehensive subcategory testing—(1) Oncogenicity—(i) Required testing.* (A) When required under paragraph (d)(1)(i), an oncogenicity test shall be conducted with the substance identified in paragraph (e)(1) or (e)(3) in accordance with § 798.3300 of this chapter except for the provisions of paragraphs (b)(1)(i) and (b)(6)(i) of § 798.3300.

(B) For the purpose of this section, the following provisions also apply:

(1) *Animal selection.* Tests shall be conducted in both rats and mice.

(2) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(ii) *Reporting requirements.* (A) The oncogenicity test required under paragraph (g)(1) of this section shall be completed and a final report submitted to EPA within 53 months after the effective date of this section or after the date of EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of this section or after EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section, until the final report is submitted to EPA.

(2) *Subchronic oral toxicity—(i) Required testing.* (A) When required under paragraph (d)(1)(i) of this section, subchronic oral toxicity testing shall be conducted with the test substance identified in paragraph (e)(1) or (e)(3) of

this section in accordance with § 798.2650 of this chapter except for paragraphs (e)(1)(i) and (e)(7)(i) of § 798.2650.

(B) For the purpose of this section the following provisions also apply:

(1) *Animal selection.* Testing shall be conducted in both rats and mice.

(2) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(ii) *Reporting requirements.* (A) The subchronic oral toxicity test shall be completed and the final report submitted to EPA within 12 months after the effective date of this section or within 12 months after EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(B) An interim progress report shall be submitted to EPA for the oral subchronic toxicity test 6 months after the effective date of this section or 6 months after EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(3) *Mutagenic effects—gene mutation—(i) Required testing.* (A) When required under paragraph (d)(1)(i) of this section, a test for gene mutation in *Salmonella typhimurium* (Ames test) shall be conducted with the test substance identified in paragraph (e)(1) or (e)(3) of this section in accordance with § 798.5265 of this chapter.

(B)(1) If a test substance produces a negative result in the assay conducted pursuant to paragraph (g)(3)(i)(A) of this section, a test for detection of gene mutation in somatic cells in culture shall be conducted with that test substance in accordance with § 798.5300 except for paragraph (d)(3)(i) of § 798.5300.

(2) For the purpose of this section, the following provisions also apply:

(i) *Cell line selection.* L5178Y mouse lymphoma cells shall be used for the test.

(ii) *Locus to be examined.* Mutations shall be measured at the thymidine kinase locus.

(C)(1) If a test substance produces a positive or equivocal result in the assay conducted pursuant to paragraph (g)(3)(i)(A) or in the assay conducted pursuant to paragraph (g)(3)(i)(B)(1) of this section, a sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted with that test substance in accordance with § 798.5275 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5275.

(2) For the purpose of this section, the following provisions also apply:

(i) *Route of administration.* Exposure to the test substance shall be by the oral route.

(ii) [Reserved]



(D)(1) A test substance shall be tested in either the mouse visible specific locus assay (MVSL) or the mouse biochemical specific locus assay (MBSL), if that test substance exhibits a positive test result in the sex-linked recessive lethal assay conducted pursuant to paragraph

(g)(3)(i)(C)(1) of this section, and if, after a review, EPA issues a Federal Register notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated. The MVSL and MBSL shall be conducted in accordance with § 798.5200 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5200 or with § 798.5195 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5195, respectively.

(2) For the purpose of this section, the following provisions shall also apply:

(i) *Route of administration.* The test substance shall be administered to the test animals orally by gavage.

(ii) [Reserved]

(ii) *Reporting requirements.* (A)(1) The Ames test shall be completed and the final report submitted to EPA within 6 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(2) If required, the somatic cells in culture assay shall be completed and the final report submitted to EPA within 10 months after the effective date of this section or after the date of EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section. An interim progress report shall be submitted within 6 months after the effective date of this section or after the date of EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(3) If required, the *Drosophila* sex-linked recessive lethal assay shall be completed and the final report submitted to EPA within 22 months after the effective date of this section or after the date of EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section. If required, an interim progress report shall be submitted within 16 months after the effective date of this section or after the date of EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(4) If required, the MVSL or the MBSL shall be completed and the final report submitted to EPA within 51 months of the date of EPA's notification of the test sponsor by certified letter or Federal Register notice under paragraph (g)(3)(i)(D)(1) of this section that testing shall be initiated. Interim progress reports for the MVSL or MBSL, if

required, shall be submitted to EPA at 6-month intervals, beginning 6 months after EPA's notification of the test sponsor that testing shall be initiated, until the applicable final report is submitted to EPA.

(4) *Mutagenic effects—chromosomal aberration—(i) Required testing.* (A)(1) When required under paragraph (d)(1)(i), an *in vitro* mammalian cytogenetics test shall be conducted with the test substance identified in paragraph (e)(1) or (e)(3) of this section in accordance with § 798.5375 of this chapter, except for the provisions of paragraph (d)(3) of § 798.5375.

(2) For the purpose of this section, the following provisions also apply:

(i) *Cell line.* Chinese hamster ovary cells shall be used for the assay.

(ii) [Reserved]

(B)(1) If a test substance produces a negative result in the *in vitro* cytogenetics test conducted pursuant to paragraph (g)(4)(i)(A)(1) of this section, an *in vivo* mammalian bone marrow cytogenetics test shall be conducted with that test substance in accordance with § 798.5385 of this chapter, except for the provisions of paragraphs (d)(3) and (d)(5)(iii) of § 798.5385.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal species.* The mouse shall be used for the test.

(ii) *Route of administration.* The test substance shall be administered orally by gavage.

(C)(1) If a test substance produces a positive or equivocal result in either the *in vitro* or the *in vivo* cytogenetics test conducted pursuant to paragraphs (g)(4)(i)(A)(1) or (g)(4)(i)(B)(1) of this section, a rodent dominant-lethal assay shall be conducted with that test substance in accordance with § 798.5450 of this chapter, except for the provisions of paragraphs (d)(3)(i) and (d)(5)(iii) of § 798.5450.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Mice shall be used as the test species. Strains with low background dominant lethality, high frequency of pregnancy and high implant numbers are recommended.

(ii) *Route of administration.* The test substance shall be administered orally by gavage.

(D)(1) A rodent heritable translocation assay shall be conducted with a test substance if the dominant-lethal assay conducted for that test substance pursuant to paragraph (g)(4)(i)(C) of this section produces a positive result, and if, after a review, EPA issues a Federal Register notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated. This test shall

be conducted in accordance with § 798.5460 of this chapter except for the provisions of paragraphs (d)(3)(i) and (d)(5)(iii) of § 798.5460.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Mice shall be used as the test species.

(ii) *Route of administration.* The test substance shall be administered orally by gavage.

(ii) *Reporting requirements.* (A)(1) The *in vitro* mammalian cytogenetics test shall be completed and the final report submitted to EPA within 10 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(2) If required, the *in vivo* mammalian bone-marrow cytogenetics test shall be completed and the final report submitted to EPA within 24 months after the effective date of this section or after EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(3) If required, the dominant-lethal assay shall be completed and the final report submitted to EPA within 36 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(4) If required, the heritable translocation assay shall be completed and the final report submitted to EPA within 25 months after the date of EPA's notification of the test sponsor under paragraph (g)(4)(i)(D)(1) of this section that testing shall be initiated.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after initiation of the *in vitro* cytogenetics test and, if required, beginning 6 months after the initiation of the *in vivo* cytogenetics test, the rodent dominant lethal test, and the rodent heritable translocation test, until the applicable final reports are submitted to EPA.

(5) *Developmental toxicity—(i) Required testing.* (A) When required under paragraph (d)(1)(i) of this section, a developmental toxicity study shall be conducted with the test substance identified in paragraph (e)(1) or (e)(3) of this section in accordance with § 798.4900 of this chapter, except for the provisions of paragraphs (e)(1)(i) and (e)(5) of § 798.4900.

(B) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in rats and mice. Commonly used laboratory strains shall be employed. The strain shall not have a



low fecundity and shall preferably be characterized for its sensitivity to developmental toxins.

(2) *Route of administration.* The test substance shall be administered to the test animals orally by gavage. The test substance shall be administered approximately the same time each day.

(ii) *Reporting requirements.* (A) The developmental toxicity study required under paragraph (g)(5)(i)(A) of this section shall be completed and a final report submitted to EPA within 12 months of the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(6) *Reproductive and fertility effects—*  
(i) *Required testing.* (A) When required under paragraph (d)(1)(i) of this section, a reproduction and fertility study shall be conducted with the test substance identified in paragraph (e)(1) or (e)(3) of this section in accordance with § 798.4700 of this chapter, except for the provisions of paragraphs (c)(1)(i), (c)(5)(i)(A) and (c)(5)(ii) of § 798.4700.

(B) For the purpose of this section, the following provisions also apply:

(1) *Animal selection.* The rat shall be the test species. Strains with low fecundity shall not be used.

(2) *Route of administration.* The test substance shall be administered to the test animals orally by gavage.

(ii) *Reporting requirements.* (A) The reproductive and fertility effects study required under paragraph (g)(6)(i)(A) of this section shall be completed and a final report submitted to EPA within 29 months of the effective date of this section or of the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section, until the final report is submitted to EPA.

(7) *Neurotoxicity—*(i) *Required testing.* (A)(1) When required under paragraph (d)(1)(i) of this section, an acute and subchronic functional observation battery shall be conducted with the test substance identified in paragraph (e)(1) or (e)(3) of this section in accordance with § 798.6050 of this chapter except for the provisions of

paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6050.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats. Standard strains should be used. The potential for combined studies should be considered.

(ii) *Duration of testing.* For the acute testing, the test substance shall be administered daily over a 5-day period; for the subchronic testing, test animals shall be exposed daily for at least 90 days.

(iii) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(B)(1) When required under paragraph (d)(1)(i) of this section, an acute and subchronic motor activity test shall be conducted with the test substance identified in paragraph (e)(1) or (e)(3) of this section in accordance with § 798.6200 of this chapter except for the provisions of paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6200.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats.

(ii) *Duration of testing.* For the acute testing, the test substance shall be administered daily over a 5-day period; for the subchronic testing, test animals shall be exposed daily for at least 90 days.

(iii) *Route of administration.* Test animals shall be exposed to the test substance orally by gavage.

(C)(1) When required under paragraph (d)(1)(i), a neuropathology test shall be conducted with the test substance identified in paragraphs (d) or (e) of this section in accordance with § 798.6400 of the chapter except for the provisions of paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6400.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats.

(ii) *Duration of testing.* Animals shall be exposed for at least a 90-day period.

(iii) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(ii) *Reporting requirements.* (A) The neurotoxicity tests required under paragraphs (g)(7)(i)(A), (g)(7)(i)(B), and (g)(7)(i)(C) of this section shall be completed and final reports submitted to EPA within 18 months of the effective date of this section or of the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section, until the final report is submitted to EPA.

(B) Interim progress reports for these neurotoxicity tests shall be submitted to

EPA at 6-month intervals, beginning 6 months after the effective date of this section or of the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section, until the final report is submitted to EPA.

(h) *Required testing and reporting requirements for screening subcategory testing—*(1) *Subchronic oral toxicity—*(i) *Required testing.* (A) When required under paragraph (d)(1)(ii) of this section, subchronic oral toxicity testing shall be conducted with the test substance identified in paragraph (e)(2) or (e)(3) of this section in accordance with § 798.2650 of this chapter except for paragraphs (e)(1)(i) and (e)(7)(i) of § 798.2650.

(B) For the purpose of this section the following provisions also apply:

(1) *Animal selection.* Testing shall be conducted in rats.

(2) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(ii) *Reporting requirements.* (A) The subchronic oral toxicity test shall be completed and the final report submitted to EPA within 12 months after the effective date of this section or after EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(B) An interim progress report shall be submitted to EPA for the oral subchronic toxicity test at 6 months after the effective date of this section or after EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(2) *Mutagenic effects—gene mutation—*(i) *Required testing—*(A) When required under paragraph (d)(1)(ii) of this section, a test for gene mutation in *Salmonella typhimurium* (Ames test) shall be conducted with the test substance identified in paragraph (e)(2) or (e)(3) of this section in accordance with § 798.5265 of this chapter.

(B)(1) When required under paragraph (d)(1)(ii) of this section, a test for detection of gene mutation in somatic cells in culture shall be conducted with the test substance identified in paragraph (e)(2) of this section in accordance with § 798.5300 except for paragraph (d)(3)(i) of § 798.5300.

(2) For the purpose of this section, the following provisions also apply:

(i) *Cell line selection.* L5178Y mouse lymphoma cells shall be used for the test.

(ii) *Locus to be examined.* Mutations shall be measured at the thymidine kinase locus.



(ii) *Reporting requirements.* (A)(1) The Ames test shall be completed and the final report submitted to EPA within 6 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(2) The somatic cells in culture assay shall be completed and the final report submitted to EPA within 10 months after the effective date of this section or after the date of EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section. An interim progress report shall be submitted within 6 months after the effective date of this section or after the date of EPA's notification of manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(3) *Mutagenic effects—chromosomal aberration—(i) Required testing.* (A)(1) When required under paragraph (d)(1)(ii) of this section, an *in vitro* mammalian cytogenetics test shall be conducted with the test substance identified in paragraph (e)(2) or (e)(3) of this section in accordance with § 798.5375 of this chapter, except for the provisions of paragraph (d)(3) of § 798.5375.

(2) For the purpose of this section, the following provisions also apply:

(i) *Cell line.* Chinese hamster ovary cells shall be used for the assay.

(ii) [Reserved]

(B)(1) When required under paragraph (d)(1)(ii) of this section, an *in vivo* mammalian bone marrow cytogenetics test shall be conducted with the test substance identified in paragraph (e)(2) of this section in accordance with § 798.5385 of this chapter, except for the provisions of paragraphs (d)(3) and (d)(5)(iii) of § 798.5385.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal species.* The mouse shall be used for the test.

(ii) *Route of administration.* The test substance shall be administered orally by gavage.

(ii) *Reporting requirements.* (A)(1) The *in vitro* mammalian cytogenetics test shall be completed and the final report submitted to EPA within 10 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(2) The *in vivo* mammalian bone-marrow cytogenetics test shall be completed and the final report submitted to EPA within 24 months after the effective date of this section or after EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(4) *Developmental toxicity—(i) Required testing.* (A)(1) When required under paragraph (d)(1)(ii) of this section, the test substance listed in paragraph (e)(2) or (e)(3) of this section shall be tested in the preliminary developmental toxicity screen in accordance with § 798.4420 of this chapter, except for the provisions of paragraphs (d)(1)(i) and (d)(5) of § 798.4420.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal species.* Rats shall be used for the test. The strain should be commonly used and should not have low fecundity.

(ii) *Route of administration.* The test substance shall be administered orally by gavage.

(B) [Reserved]

(ii) *Reporting requirements.* (A) The preliminary developmental toxicity screen shall be completed and the final report submitted to EPA within 12 months of the effective date of this section or of the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of this section or after the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(5) *Neurotoxicity—(i) Required testing.* (A)(1) When required under paragraph (d)(1)(ii) of this section, a subchronic functional observation battery shall be conducted with the test substance identified in paragraph (e)(2) or (e)(3) of this section in accordance with § 798.6050 of this chapter except for the provisions of paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6050.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats. Standard strains should be used. The potential for combined studies should be considered.

(ii) *Duration of testing.* Test animals shall be exposed daily for at least 90 days.

(iii) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(B)(1) When required under section (d)(1)(ii), a subchronic motor activity test shall be conducted with the test substance identified in paragraph (e)(2) or (e)(3) of this section in accordance

with § 798.6200 of this chapter except for the provisions of paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6200.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats.

(ii) *Duration of testing.* Test animals shall be exposed daily for at least 90 days.

(iii) *Route of administration.* Test animals shall be exposed to the test substance orally by gavage.

(C)(1) When required under paragraph (d)(1)(ii) of this section, a neuropathology test shall be conducted with the test substance identified in paragraph (e)(2) or (e)(3) of this section in accordance with § 798.6400 of the chapter except for the provisions of paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6400.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats.

(ii) *Duration of testing.* Animals shall be exposed for at least a 90-day period.

(iii) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(ii) *Reporting requirements.* (A) The neurotoxicity tests required under paragraphs (h)(5)(i)(A), (h)(5)(i)(B), and (h)(5)(i)(C) of this section shall be completed and final reports submitted to EPA within 18 months of the effective date of this section or of the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section.

(B) Interim progress reports for these neurotoxicity tests shall be submitted to EPA at 6-month intervals, beginning at 6 months after the effective date of this section or of the date of EPA's notification of the manufacturers pursuant to paragraph (d)(1)(iii) of this section, until the final report is submitted to EPA.

(i) *Required testing and reporting requirements for health effect-specific subcategory mutagenic effects testing—(1) Gene mutation—(i) Required testing.* (A) When required under paragraph (d)(2)(i) of this section, a test for gene mutation in *Salmonella typhimurium* (Ames test) shall be conducted with the test substance identified in paragraph (e)(4) of this section in accordance with § 798.5265 of this chapter.

(B)(1) If a test substance produces a negative result in the assay conducted pursuant to paragraph (i)(1)(i)(A) of this section, a test for detection of gene mutation in somatic cells in culture shall be conducted with that test substance in



accordance with § 798.5300 except for paragraph (d)(3)(i) of § 798.5300.

(2) For the purpose of this section, the following provisions also apply:

(i) *Cell line selection.* L5178Y mouse lymphoma cells shall be used for the test.

(ii) *Locus to be examined.* Mutations shall be measured at the thymidine kinase locus.

(C)(1) If a test substance produces a positive or equivocal result in the assay conducted pursuant to paragraph (i)(1)(i)(A) or in the assay conducted pursuant to paragraph (i)(1)(i)(B) of this section, a sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted with that test substance in accordance with § 798.5275 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5275.

(2) For the purpose of this section, the following provisions also apply:

(i) *Route of administration.* Exposure to the test substance shall be by the oral route.

(ii) [Reserved]

(D)(1) A test substance shall be tested in either the MVSL or the MBSL, if that test substance exhibits a positive test result in the sex-linked recessive lethal assay conducted pursuant to paragraph (i)(1)(i)(C) of this section, and if, after a review, EPA issues a Federal Register notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated. The MVSL and MBSL shall be conducted in accordance with § 798.5200 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5200 or with § 798.5195 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5195, respectively.

(2) For the purpose of this section, the following provisions shall also apply:

(i) *Route of administration.* The test substance shall be administered to the test animals orally by gavage.

(ii) [Reserved]

(ii) *Reporting requirements.* (A)(1) The Ames test shall be completed and the final report submitted to EPA within 6 months after the effective date of this section.

(2) If required, the somatic cells in culture assay shall be completed and the final report submitted to EPA within 10 months after the effective date of this section. An interim progress report shall be submitted within 6 months after the effective date of the final rule.

(3) If required, the *Drosophila* sex-linked recessive lethal assay shall be completed and the final report submitted to EPA within 22 months after the effective date of this section. If required, an interim progress report shall be

submitted within 16 months after the effective date of the final rule.

(4) If required, the MVSL test or the MBSL shall be completed and the final report submitted to EPA within 51 months of the date of EPA's notification of the test sponsor by certified letter or Federal Register notice under paragraph (i)(1)(i)(D) of this section that testing shall be initiated. Interim progress reports for the MVSL or MBSL test, if required, shall be submitted to EPA at 6-month intervals, beginning at 6 months after EPA's notification of the test sponsor that testing shall be initiated, until the applicable final report is submitted to EPA.

(2) *Chromosomal aberration—(i) Required testing.* (A)(1) When required under paragraph (d)(2)(i) of this section, an *in vitro* mammalian cytogenetics test shall be conducted with the test substance identified in paragraph (e)(4) of this section in accordance with § 798.5375 of this chapter, except for the provisions of paragraph (d)(3) of § 798.5375.

(2) For the purpose of this section, the following provisions also apply:

(i) *Cell line.* Chinese hamster ovary cells shall be used for the assay.

(ii) [Reserved]

(B)(1) If a test substance produces a negative result in the *in vitro* cytogenetics test conducted pursuant to paragraph (i)(2)(i)(A) of this section, an *in vivo* mammalian bone marrow cytogenetics test shall be conducted with that test substance in accordance with § 798.5385 of this chapter, except for the provisions of paragraphs (d)(3) and (d)(5)(iii) of § 798.5385.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal species.* The mouse shall be used for the test.

(ii) *Route of administration.* The test substance shall be administered orally by gavage.

(C)(1) If a test substance produces a positive or equivocal result in either the *in vitro* or the *in vivo* cytogenetics test conducted pursuant to paragraphs (i)(2)(i)(A) or (i)(2)(i)(B) of this section, a rodent dominant-lethal assay shall be conducted with that test substance in accordance with § 798.5450 of this chapter, except for the provisions of paragraphs (d)(3)(i) and (d)(5)(iii) of § 798.5450.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Mice shall be used as the test species. Strains with low background dominant lethality, high frequency of pregnancy and high implant numbers are recommended.

(ii) *Route of administration.* The test substance shall be administered orally by gavage.

(D)(1) A rodent heritable translocation assay shall be conducted with the test substance if the dominant-lethal assay conducted for the test substance pursuant to paragraph (i)(2)(i)(A) of this section produces a positive result, and if, after a review, EPA issues a Federal Register notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated. This test shall be conducted in accordance with § 798.5460 of this chapter except for the provisions of paragraphs (d)(3)(i) and (d)(5)(iii) of § 798.5460.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Mice shall be used as the test species.

(ii) *Route of administration.* The test substance shall be administered orally by gavage.

(ii) *Reporting requirements.* (A)(1) The *in vitro* mammalian cytogenetics test shall be completed and the final report submitted to EPA within 10 months after the effective date of this section.

(2) If required, the *in vivo* mammalian bone-marrow cytogenetics test shall be completed and the final report submitted to EPA within 24 months after the effective date of this section.

(3) If required, the dominant-lethal assay shall be completed and the final report submitted to EPA within 36 months after the effective date of this section.

(4) If required, the heritable translocation assay shall be completed and the final report submitted to EPA within 25 months after the date of EPA's notification of the test sponsor under paragraph (i)(2)(i)(D) of this section that testing shall be initiated.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after initiation of the *in vitro* cytogenetics test and, as applicable, beginning 6 months after the initiation of the *in vivo* cytogenetics test, the rodent dominant lethal test, and the rodent heritable translocation test, until the applicable final reports are submitted to EPA.

(j) *Required testing and reporting requirements for health effect-specific testing of specific substances—(1) Subchronic toxicity—(i) Required testing.* (A) When required under paragraph (d)(3)(i) of this section, subchronic oral toxicity testing shall be conducted with the test substance identified in paragraph (d)(3)(i) of this section in accordance with § 798.2650 of this chapter except for paragraphs (e)(1)(i) and (e)(7)(i) of § 798.2650.



(B) For the purpose of paragraph (j)(1)(i)(A) of this section the following provisions also apply:

(1) *Animal selection.* Testing shall be conducted in both rats and mice.

(2) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(ii) *Reporting requirements.* (A) The subchronic oral toxicity test shall be completed and the final report submitted to EPA within 12 months after the effective date of this section.

(B) An interim progress report shall be submitted to EPA for the oral subchronic toxicity test at 6 months after the effective date of this section.

(2) *Reproductive and fertility effects—(i) Required testing.* (A) When required under paragraph (d)(3)(i) of this section, a reproduction and fertility study shall be conducted with the test substance identified in paragraph (d)(3)(i) of this section in accordance with § 798.4700 of this chapter, except for the provisions of paragraphs (c)(1)(i), (c)(5)(i)(A) and (c)(5)(ii) of § 798.4700.

(B) For the purpose of this section, the following provisions also apply:

(1) *Animal selection.* The rat shall be the test species. Strains with low fecundity shall not be used.

(2) *Route of administration.* The test substance shall be administered to the test animals orally by gavage.

(ii) *Reporting requirements.* (A) The reproductive and fertility effects study required under paragraph (j)(2)(i)(A) of this section shall be completed and a final report submitted to EPA within 29 months of the effective date of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after the effective date of this section.

(3) *Neurotoxicity—(i) Required testing.* (A)(1) When required under paragraph (d)(3)(i) of this section, an acute and subchronic functional observation battery shall be conducted with the test substance identified in paragraph (d)(3)(i) of this section in accordance with § 798.6050 of this chapter except for the provisions of paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6050.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats. Standard strains should be used. The potential for combined studies should be considered.

(ii) *Duration of testing.* For the acute testing, the test substance shall be administered daily over a 5-day period; for the subchronic testing, test animals shall be exposed daily for at least 90 days.

(iii) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(B)(1) When required under paragraph (d)(3)(i) of this section, an acute and subchronic motor activity test shall be conducted with the test substance identified in paragraph (d)(3)(i) of this section in accordance with § 798.6200 of this chapter except for the provisions of paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6200.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats.

(ii) *Duration of testing.* For the acute testing, the test substance shall be administered daily over a 5-day period; for the subchronic testing, test animals shall be exposed daily for at least 90 days.

(iii) *Route of administration.* Test animals shall be exposed to the test substance orally by gavage.

(C)(1) When required under paragraph (d)(3)(i) of this section, a neuropathology test shall be conducted with the test substance identified in paragraph (d)(3)(i) of this section in accordance with § 798.6400 of the chapter except for the provisions of paragraphs (d)(1)(i), (d)(5) and (d)(6) of § 798.6400.

(2) For the purpose of this section, the following provisions also apply:

(i) *Animal selection.* Testing shall be performed in laboratory rats.

(ii) *Duration of testing.* Animals shall be exposed for at least a 90-day period.

(iii) *Route of administration.* Animals shall be exposed to the test substance orally by gavage.

(ii) *Reporting requirements.* (A) The neurotoxicity tests required under paragraphs (j)(3)(i)(A), (j)(3)(i)(B), and (j)(3)(i)(C) of this section shall be completed and final reports submitted to EPA within 18 months of the effective date of this section.

(B) Interim progress reports for these neurotoxicity tests shall be submitted to EPA at 6-month intervals, beginning at 6 months after (the effective date of this section) until the final report is submitted to EPA.

## VI. Issues For Comment

### A. Route of Exposure for Proposed Testing

This proposed rule specifies the TSCA health effects test guidelines and the oral route of exposure for all whole-animal testing required for members of the chemical category of glycidyls. EPA is proposing that gavage administration be used for the following types of studies: oncogenicity, subchronic (90-day) toxicity, *in vivo* cytogenetics,

dominant lethal, heritable translocation, mouse visible or biochemical specific locus, developmental toxicity, reproductive toxicity, and Chernoff screening test for reproductive toxicity.

Although EPA believes that most human exposure to these substances will occur by the dermal and/or inhalation routes, EPA has proposed the oral route for testing for the following reasons. Meaningful dermal studies may be difficult, if not impossible, to conduct because of the general properties of irritancy to skin and the ability to elicit skin sensitization reactions demonstrated by many members of this chemical category. Most of the proposed test substances have low vapor pressures, making inhalation studies difficult, if not impossible, to conduct and quantitation of actual dose levels less accurate than possible in oral studies. EPA solicits comments on the proposed routes of exposure for all whole-animal testing under this rule.

### B. Subchronic/Oncogenicity Testing

Many of the subchronic studies conducted as range-finding, dose-setting studies for oncogenicity bioassays submitted to EPA have been deficient in evaluation of several important longer-term health effects. Because EPA is interested in a more comprehensive evaluation of these effects, EPA has proposed that the test standard for proposed oncogenicity testing of the glycidyls consist of oncogenicity bioassays by gavage, conducted according to 40 CFR 798.3300, and subchronic toxicity testing by gavage, conducted according to 40 CFR 798.2650. Alternatively, EPA has considered proposing the TSCA health effect testing guideline for combined chronic toxicity/oncogenicity (40 CFR 798.3320), using administration by gavage, as the test standard. EPA solicits public comment on the relative merits of these two approaches.

### C. Mutagenicity Testing

The current mutagenicity testing scheme used in TSCA section 4(a) test rules and proposed in modified form for this chemical category is outlined in Unit V.B.2. of this preamble. Revisions to this testing scheme are under review within EPA. Specifically, consideration is being given to eliminating the requirement for the *in vitro* mammalian cytogenetics test (40 CFR 798.5375), and eliminating all triggers in the first tier of tests. This would result in a requirement for three tests in the first tier (Ames assay, 40 CFR 798.5265; mammalian cells in culture test for gene mutation, 40 CFR 798.5300; and an *in vivo* assay for



chromosomal aberrations, 40 CFR 798.5385, or an *in vivo* assay for micronuclei, 40 CFR 798.5395). There would be no triggering of tests within the first tier; EPA would review the data from all three tests to determine whether one or both of the second-tier tests (sex-linked recessive lethal test in *Drosophila*, 40 CFR 798.5275 or other test(s), as appropriate, and rodent dominant lethal test, 40 CFR 798.5450) should be initiated.

The same EPA reviews of the data obtained from the second-tier tests described in Unit V.B.2. of this preamble would determine if further oncogenicity or mutagenicity testing, respectively, would be required.

EPA solicits public comment on the relative merits of the mutagenicity testing scheme proposed for this chemical category and its contemplated revision.

#### D. Developmental Toxicity Testing

As discussed in Unit V.B.3. of this preamble, EPA has proposed the Chernoff screening test (40 CFR 798.4420) for representative test substances from subcategories with testing triggered when annual production volume exceeds 1 million pounds, but is less than 10 million pounds. By contrast, EPA has proposed to require developmental toxicity testing in two species using the developmental toxicity study (40 CFR 798.4900) for substances for which testing is proposed based on preliminary hazard data and for a representative member of any subcategory whose annual production volume equals or exceeds 10 million pounds.

EPA is considering replacing the proposed Chernoff screening test (40 CFR 798.4420) requirement with a requirement for testing with one species in the complete developmental toxicity study (40 CFR 798.4900). EPA believes that such a one-species test may prove more effective for screening purposes than the proposed Chernoff test, and invites public comment on the relative merits of these two screening approaches.

#### E. Additional Existing Test Data

As discussed in Unit I.I.F. of this preamble, EPA has reviewed (Refs. 2 and 3) all of the health effects data for the members of the chemical category of glycidyls available to EPA at the time of rule development. Included in this review were studies submitted to EPA by industry under section 8(d) or (e) of TSCA, studies submitted to EPA on a voluntary basis, and studies appearing in the open scientific literature. In many cases, EPA was unable to evaluate

studies because the nature of the test substance was not adequately characterized. EPA solicits the submission of any additional health effects studies not included in this preamble or contained in References 2 or 3, together with an adequate description of the test substance. Such a description should include the percent purity established by a cited analytical procedure, the identity of any major impurities established by cited methodologies, an estimate of the average molecular weight of the test substance and methods used for estimation, and the Chemical Abstracts Service Registry Number (CAS No.) for the test substance. This information will be used by EPA to determine whether adequate data already exist to meet some of the testing requirements proposed here.

#### F. Future Testing of Oligomers and Polymers

This proposal deals only with test requirements for monomeric members of the chemical class of glycidyls. EPA believes that any toxicity elicited as a result of exposure to high molecular weight polymers would primarily be due to the action of residual monomers and oligomers because of the expected poor absorption of higher molecular weight species. This assumption has yet to be verified for this chemical class. Further examination of this assumption is important given that the human exposure to liquid epoxy resins containing oligomers and polymers far exceeds exposure to monomers. In addition, many of the new chemical substances for which Premanufacture Notices (PMN's) have been submitted to EPA under section 5 of TSCA are oligomers or polymers of the glycidyls, and data are lacking for existing oligomers and polymers of this class for use as analogue data for new substances under PMN review.

If the criteria for TSCA section 4 testing for glycidyls were based solely on data needs for the Premanufacture Review program, bisphenol A diglycidyl ether and its derivatives would represent the highest priority candidates for testing. Glycidyl acrylate (or methacrylate) would represent the second priority candidates. The TSCA section 5 data needs for health effects testing of bisphenol A diglycidyl ether are consistent with the testing scheme outlined in this proposed rule.

In performing risk assessments for regulatory decision-making under section 5 of TSCA, and in evaluating the safety of existing substances that are made by polymerization and may contain significant quantities of low-

molecular-weight, but non-monomeric species, it is crucial to develop an understanding of the relationships between toxicity, molecular weight, and absorption potential of oligomeric and polymeric species.

In light of data needs for the evaluation of both new and existing substances which are oligomeric or polymeric in nature, EPA is interested in evaluating health effects test data submitted by industry on oligomeric glycidyl compounds that are well characterized with respect to molecular weight distribution, epoxy equivalent weight, and purity.

EPA believes that the oligomeric substances of greatest interest for testing would include the homopolymers of bisphenol A diglycidyl ether. For example, with respect to oncogenicity testing, a lifetime cancer bioassay might be conducted in two species by an appropriate route of exposure simultaneously with a pure monomeric glycidyl compound and two or three molecular weight ranges of the homopolymer of that monomer. Alternatively, it might be possible to conduct "limited" lifetime cancer bioassays to screen for potential oncogenicity for such a series of glycidyl compounds. Such bioassays would be "limited" in the sense that only one sex and one species of rodent might be used for such screening purposes. While such an approach would not provide a definite measure of oncogenic potential, it would allow for a relative estimate when the data from each glycidyl oligomer tested were compared with the effects elicited by other oligomers of the same monomer.

EPA recognizes that obtaining pure dimer, trimer, etc., of a glycidyl monomer might be difficult. However, if several molecular weight ranges of the substance were prepared, and the percentages of individual species in each sample were determined by gel permeation chromatography, for example, EPA believes that results of toxicity studies on such materials would be meaningful.

EPA solicits comment on the feasibility of such an approach for future rulemaking under section 4 of TSCA for oligomers and polymers of the chemical category of glycidyl and its derivatives, and requests suggestions for alternative approaches. EPA also requests comment on the suitability of a testing Consent Order under TSCA section 4 as the method of choice for obtaining test data on these oligomers and polymers, and welcomes the current or future submission of any such test data



### G. Representative Test Substance

In this proposal, EPA has attempted to balance testing needs with the cost of testing. Therefore, EPA has lessened testing requirements in some instances by specifying one substance within a subcategory as the test substance to fulfill testing requirements. EPA solicits comments on whether instead of this approach, EPA should allow a manufacturer who does not make the substance specified for testing to opt out of joint testing if that manufacturer conducts testing of the substance the manufacturer makes. The other manufacturers would still be required to conduct joint testing of the representative test substance designated by EPA.

### H. Production Volume Triggers for Subcategory Testing

As discussed in Unit III. of this preamble, EPA is proposing to use the annual production data submitted under the proposed TSCA section 8(a) rule for glycidyls to trigger testing of a representative member of a subcategory in either a screening battery or comprehensive battery of tests, which are described in Unit V.A. EPA has proposed using the aggregate annual production volume of the subcategory as the criterion, with subcategories having an aggregate annual production volume of at least 1 million pounds but less than 10 million pounds required to test a representative member in the screening battery, and subcategories having an aggregate annual production volume of 10 million pounds or more required to test a representative member in the comprehensive battery.

EPA has considered using other criteria to trigger subcategory testing. Using the additive production/importation volumes of subcategory members as the only triggering criterion might conceivably result in the triggering of testing of a subcategory containing a great number of members whose aggregate production reached the triggering value, but for which the production volumes of the individual members would be quite low. EPA, therefore, considered an alternative criterion for triggering testing based not on aggregate subcategory production volume but rather on average annual production volume for subcategory members. Rather than a single criterion of aggregate annual subcategory production of at least one million pounds but less than 10 million pounds for triggering the screening battery of testing, the condition to be met might be that the average subcategory member production volume (aggregate

subcategory production volume divided by the number of subcategory members) must be greater than a minimum value (for example, the average value could be set at 1 million pounds). Similarly, the criterion for the triggering of comprehensive testing would consist of an average subcategory member production volume reaching a minimum value (for example, the average value could be set at 10 million pounds).

EPA invites comments on the relative merits of these two approaches for triggering of subcategory testing.

EPA also welcomes comments on the following, as well as suggestions for other triggering criteria:

1. Triggering testing for a subcategory if at least one representative of the subcategory totals 1 million pounds of production per year.

2. Triggering testing for a subcategory by means of exposure-based criteria such as workers exposed, consumers exposed, etc., in addition to production-based criteria.

### I. Comprehensive Testing Trigger

EPA has defined two production-level triggers, one at one million pounds for screening level testing and one at 10 million pounds for oncogenicity and comprehensive level testing. EPA solicits comment on whether 10 million pounds comports with manufacturers' ability to pay for the comprehensive level of testing. In addition, EPA solicits comments on the value of the information derived from comprehensive testing relative to the burden imposed when selecting this trigger. Is it appropriate to use 10 million pounds to trigger testing based on a high production/high exposure concern? If an exposure value should be included, what should it be and how could EPA apply it as a triggering mechanism?

### J. Interchangeability of Substances for End Uses

EPA is aware of the interchangeability of several of the glycidyls for the same end use, and has considered the available data regarding this interchangeability in EPA's economic analysis of this proposed rule presented in Unit VII. of the preamble.

To gain a greater understanding of the interchangeability of glycidyls, so that this factor can play the appropriate role in evaluations of the economic impact of this proposed rule, EPA is requesting the submission of additional data relating to interchangeability.

### K. Subcategorization Scheme

EPA has attempted to balance the costs of testing with the need to conduct risk assessments on these chemicals.

Accordingly, to ease the testing costs, EPA has not proposed testing of each member of the category. Instead, EPA has used SAR to define subcategories and has proposed that, generally, data be developed on only one member of a particular subcategory. This would be sufficient testing, however, because wherever possible, EPA would use the data on the tested member to assess the risks of all members of the subcategory. EPA has considered alternatives, such as using fewer subcategories, which would further lessen the burden of testing. However, using fewer subcategories would also mean that the substances within each subcategory would be less structurally similar, and therefore using the data on one test substance to represent the toxicity of all members of the subcategory would become more difficult to justify. While EPA has tried to accommodate these two objectives, EPA recognizes that there may be other workable approaches. Therefore, EPA is interested in constructive suggestions of how to reduce the testing burden and reduce the complexity of this rule, while providing for sufficient data to assess the risks posed by the entire category of glycidyls. EPA is soliciting comment on alternative subcategorizations based on testing burden and the usefulness of the test data.

### VII. Economic Analysis of Proposed Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis that evaluates the potential for significant adverse economic impacts on the industry as a result of the required testing. Much of the information reviewed in the economic analysis was claimed as Confidential Business Information (CBI) and, although in the record for this rulemaking as TSCA CBI Document Control No.: 20-911000066, is not available for public review. A non-CBI version of this analysis has been prepared (Ref. 14) and has been placed in the public rulemaking record for this proposed rule. The analysis is summarized below.

The total costs of the proposed immediately-required testing are estimated to range from \$12.9 to \$18.2 million, including \$10.3 to \$14.6 million in laboratory costs and \$2.6 to \$3.6 million in administrative costs. Administrative cost associated with test rules are estimated to be equal to 25 percent of the laboratory costs, and account for activities such as selecting laboratories, preparing test protocols, monitoring testing, developing cost-



sharing agreements and preparing reports to EPA. The annualized test costs (using a 7 percent cost of capital and a 15-year cost recovery period) range from \$1.4 million to \$2.0 million. Annualized costs represent the constant costs which would have to be recouped each year of the 15-year payback period to finance the testing expenditure in the first year. The annualized costs are compared with annual revenue as an indication of the potential impact of the test costs.

To simplify discussion of the test cost impacts, the substances included in this proposed rule have been divided into three different groups, based on the uses of the substances. The potential impact of the test costs on each of these three groups, and on glycidol, is discussed below.

#### *A. Epoxy Resin Intermediate and Specialty Resins*

This group includes the substances in subcategories VI and VII. Diglycidyl ether of bisphenol A, an intermediate to epoxy resins, is by far the largest volume substance in this group. The others in this group are used as epoxy modifiers, as specialty resins for aerospace applications, and as intermediates to components of acrylic coating resins.

Total estimated test costs for this group of chemicals range from \$4.6 million to \$6.5 million. The potential for adverse economic impact on the substances in this group appears to be low, due to the following factors: demand appears to be inelastic; market expectations are favorable; and unit test costs are low relative to price.

#### *B. Reactive Diluents*

Subcategories I, II, IV, and V are comprised primarily of glycidyl ethers which are used as reactive diluents for epoxy resins. Estimated total test costs for this group range from \$6.2 million to \$8.8 million. The potential for significant adverse economic impact of the test costs on the group of reactive diluents as a whole appears to be low. However, the potential for adverse economic impact on some of the lower-volume reactive diluents in the group may be significant. These conclusions are based on the following factors: demand for reactive diluents as a group appears to be relatively inelastic, but demand for some of the low-volume diluents may be significantly more elastic; and unit test costs may be somewhat high relative to price for several of the individual chemicals in the group. The adverse impacts of any potential substitutions are also reduced by the likelihood that the suppliers of the potentially affected

chemicals are also the suppliers of the probable substitutes.

#### *C. Silane Coupling Agents*

The only substance of commercial significance in subcategory III is 3-(trimethoxysilyl)propyl glycidyl ether, which is used as a silane coupling agent. Estimated total test costs for this category range from \$1.1 million to \$1.5 million. These costs are not expected to have a significant economic impact, due to the following factors: demand for 3-(trimethoxysilyl)propyl glycidyl ether appears to be somewhat inelastic; market expectations are favorable; and test costs are low relative to price. The adverse impacts of any potential substitutions are also reduced by the likelihood that the several suppliers of 3-(trimethoxysilyl)propyl glycidyl ether are also suppliers of the probable substitutes.

#### *D. Glycidol*

Estimated total test costs for glycidol range from \$0.9 million to \$1.3 million. The potential for significant impact on the glycidol market is low, because demand for this substance appears to be inelastic.

Refer to the non-CBI economic analysis found in the rulemaking record for this proposed rule for a complete discussion of test costs estimation and the potential for economic impact resulting from these tests.

#### *E. Costs of Reporting Under TSCA Section 8(a)*

In addition to the costs of testing, firms will also incur costs for reporting under TSCA section 8(a). Firms will be required to report their annual production volume of each substance subject to the test rule. This requirement represents an additional expense for each of those years in which firms are not required to report production volumes under the Inventory Update Rule, which requires reporting every fourth year. Each year's reporting will cost approximately \$35 per substance per firm, involving 0.5 hours of technical time, 0.5 hours of clerical time, and 0.2 hours of management staff per chemical per company. Additionally, each firm may incur fixed costs of \$50 annually as 1 hour of management time is spent for rule familiarization. Section 8(a) reporting costs have no effect on the conclusions discussed above concerning the potential for adverse economic impact on any of the substances subject to this rule.

#### **VIII. Availability of Test Facilities And Personnel**

EPA has determined that test facilities and personnel are available to perform the testing specified in this proposed rule (Ref. 15).

#### **IX. Public Meetings**

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting subsequent to the close of the public comment period in Washington, DC. Persons who wish to attend or to present comments at the meeting should call Mary Louise Hewlett (202) 260-8162. The meeting will be open to the public, but active participation may be limited to those persons who arrange to present comments and to designated EPA participants. Participants are requested to submit copies of their statements by the meeting date. These statements and a transcript of the meeting will become part of the record for this rulemaking.

#### **X. Comments Containing Confidential Business**

##### **Information (CBI)**

All comments will be placed in the public file unless they are clearly labeled as CBI when they are submitted. While part of the record, CBI comments will be treated in accordance with 40 CFR part 2. A sanitized version of all CBI comments, from which CBI has been deleted, should be submitted to EPA for the public file. It is the responsibility of the commenter to comply with 40 CFR part 2 in order that all materials claimed as confidential may be properly protected. This includes, but is not limited to, clearly indicating on the face of the comment (as well as on any associated correspondence) that CBI is included, and marking "CONFIDENTIAL", "TSCA CBI" or similar designation on the face of each document or attachment in the comment which contains CBI.

#### **XI. Rulemaking Record**

EPA has established a record for this rulemaking, [docket number OPTS-42051A]. This record contains the basic information considered by EPA in developing this proposal and appropriate Federal Register notices. EPA will supplement this record as necessary.

A public version of the record, from which all CBI has been deleted, is available for inspection in the OPTS Reading Room, Rm. G-004, NE Mall, 401



M St., SW., Washington, DC 20460, from 8 am to 12 noon, and from 1 pm to 4 pm, Monday through Friday, except legal holidays. The record currently includes the following information:

#### A. Supporting Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of the chemical category of glycidol and its derivatives to the Priority List (43 FR 50630, October 30, 1978).

(b) Rule requiring TSCA section 8(a) reporting on the chemical category of glycidol and its derivatives (47 FR 26992, June 22, 1982).

(c) Rule requiring TSCA section 8(d) reporting on the chemical category of glycidol and its derivatives (47 FR 38780, September 2, 1982).

(d) TSCA test guidelines cited as proposed test standards for this rule.

(e) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (54 FR 34034, August 17, 1989).

(f) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652, May 17, 1985).

(g) Notice of final rule on data reimbursement policy and procedures (48 FR 31786, July 11, 1983).

(h) Advance notice of proposed rulemaking for glycidol and its derivatives (48 FR 57562, December 30, 1983).

(i) Notice of Inventory Update Rule (51 FR 21447, June 12, 1986).

(j) Notice of Agency's first and second proposed test rules (45 FR 48510, July 18, 1980 and 46 FR 30300, June 5, 1981).

(k) Notice of proposed rule for chlorinated benzenes (45 FR 48524, July 18, 1980).

(l) Notice of proposed rule for mesityl oxide (48 FR 30699, July 5, 1983).

(m) Notice of proposed rule for cresols (48 FR 31812, July 11, 1983).

(n) Notice of proposed rule for ethyltoluenes, trimethylbenzenes, and C9 aromatic hydrocarbon fraction (43 FR 23088, May 23, 1983).

(o) Notice of final Phase I test rule for mesityl oxide (50 FR 51857, December 20, 1985).

(p) Notice of final Phase I test rule for C9 aromatic hydrocarbon fraction (50 FR 20662, May 17, 1985).

(q) Notice of test rule for diethylenetriamine (50 FR 21398, May 23, 1985).

(r) Notice of test rule for four fluoroalkenes (52 FR 21516, June 8, 1987).

(s) Notice of proposed amendment in test rules for mouse visible specific locus test requirement (53 FR 51847, December 23, 1988).

(t) Notice of final amendment in test rules for the mouse visible specific locus requirement (55 FR 12639, April 5, 1990).

(2) Communications before proposal consisting of:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(3) Reports—published and unpublished factual materials.

#### B. References

(1) USEPA. U.S. Environmental Protection Agency. Test Rules Development Branch. "Support Document for Glycidol and its Derivatives: Responses to Comments on the Advance Notice of Proposed Rulemaking" (ANPR: December 30, 1983, 48 FR 57562). (December, 1989).

(2) Syracuse Research Corporation. "Draft Final Technical Support Document: Glycidol and its Derivatives." (November 11, 1986).

(3) USEPA. U.S. Environmental Protection Agency. Test Rules Development Branch. "Support Document for Glycidol and its Derivatives: Review of Available Health Effects Data." (October, 1987).

(4) Merck. "The Merck Index (10th Edition)." Rahway, NJ: Merck and Co., Inc., page 4359. (1983).

(5) Lee, H., and Neville, K. "Epoxy resins." In: *Encyclopedia of Polymer Science and Technology*, Volume 6. N.M. Bikales, and J. Conrad, eds. New York, NY: Interscience Publishers, pages 209-271. (1967).

(6) CBI. Confidential Business Information. TSCA Document Control No. 20-874000167. Computer print-out of public and confidential portions of the TSCA section 8(d) Inventory of Chemical Substances (Updated) July 15, 1987.

(7) Personal Communication between Raymond Locke, USEPA Chemical Testing Branch, and Gabrielle Urquhart, Mathtech, Inc., July 1987.

(8) JRB Associates. "TSCA Section 4 Human Exposure Assessment: Glycidol and its Derivatives (Final Report)." (February 4, 1982).

(9) Versar, Inc. "Consumer Exposure to the Glycidols (Draft Final Report)." (December 1, 1983).

(10) NIOSH. National Institute for Occupational Safety and Health. "Criteria for a Recommended Standard: Occupational Exposure to Glycidyl Ethers." DHEW (NIOSH) Publication No. 78-166. (1978).

(11) Stinson, S. "Epoxidation advance may spur its industrial use." *Chemical and Engineering News*, page 24. (June 2, 1986).

(12) Crathorne, B., Fleiding, M., Steel, C.P., and Watts, C.D. "Organic compounds in water: analysis using coupled-column high performance liquid chromatography and soft-ionization mass spectrometry." *Environmental Science and Technology* 18:797-802. (1984).

(13) Capital Systems Group, Inc., and Dynamac Corporation, Enviro Control Division. "Draft Final Subcategorization Scheme for Glycidol Ethers and Esters." (October 26, 1984).

(14) USEPA. Economics and Technology Division. "Economic Impact Analysis of Proposed Test Rule for Glycidol and its Derivatives (Confidential and Non-Confidential Information Versions)." (September 24, 1990).

(15) Booz, Allen Hamilton, Inc., Bethesda, MD. "EPA census of the toxicological testing industry." Prepared for the Office of Policy Analysis, OTS, USEPA, Washington, DC. (June, 1990).

## XII. Other Regulatory Requirements

### A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this proposed test rule, if promulgated, is not major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e., it would not have any annual effect on the economy of at least \$100 million, would not cause a major increase in prices, and would not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

### B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 et seq., Pub. L. 96-354, September 19, 1980), EPA believes that this proposed test rule, if promulgated, would not have a significant impact on a substantial number of small businesses because: (1) There are only a small number of known small manufacturers, (2) any small processors are not expected to perform testing themselves or to participate in the organization of the testing effort, (3) they will experience only very minor cost in securing exemption from testing requirements, and (4) they are unlikely to be affected by reimbursement requirements.

The definition of small business used under TSCA section 8(a) to exempt from reporting includes any manufacturing/importing firm with annual sales, including sales of any parent firm, below \$4 million, or any firm which manufactures the chemical of concern at less than 100,000 pounds annually and has sales, including sales of any parent firm, below \$40 million.

EPA is requesting that interested parties submit comments regarding adverse economic impact which may result from testing requirements. Upon



receipt of public comments, EPA will reevaluate the determination that small firms will not be adversely affected by this rulemaking.

#### *C. Paperwork Reduction Act*

The information collection requirements contained in this proposed rule have been approved by OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and have been assigned OMB number 2070-0033.

Public reporting burden for this collection of information is estimated to average 22,370 hours per response,

including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0033), Washington, DC 20503. The final rule will respond to any

OMB or public comments on the information collection requirements.

#### **List of Subjects in 40 CFR Parts 704 and 799**

Chemicals, Chemical export, Environmental protection, Hazardous substances, Recordkeeping and reporting requirements, Testing.

Dated: October 28, 1991.

Victor J. Kimm,

*Acting Assistant Administrator for Pesticides and Toxic Substances.*

[FR Doc. 91-26749 Filed 11-6-91; 8:45 am]

**BILLING CODE 5560-50-F**



# Federal Register

Thursday  
November 7, 1991

## Part IV

### Department of Defense General Services Administration

### National Aeronautics and Space Administration

48 CFR Part 15

Federal Acquisition Regulation;  
Subcontract Pricing; Proposed Rule



## DEPARTMENT OF DEFENSE

GENERAL SERVICES  
ADMINISTRATIONNATIONAL AERONAUTICS AND  
SPACE ADMINISTRATION

## 48 CFR Part 15

[FAR Case 90-59]

Federal Acquisition Regulation;  
Subcontract Pricing

**AGENCIES:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Proposed rule.

**SUMMARY:** The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council are proposing to revise policies affecting cost analysis as they relate to subcontract cost. Review of the Defense Federal Acquisition Regulation Supplement indicated that there were policies which had value beyond use solely within the Department of Defense and should be made applicable Governmentwide.

**DATES:** Comments should be submitted to the FAR Secretariat at the address shown below on or before January 8, 1992 to be considered in the formulation of a final rule.

**ADDRESSES:** Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), ATTN: Deloris Baker, 18th & F Streets, NW., room 4041, Washington, DC 20405.

Please cite FAR case 90-59 in all correspondence related to this case.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jeremy Olson at (202) 501-3221 in reference to this FAR case. For general information, contact the FAR Secretariat, room 4041, GS Building, Washington, DC 20405, (202) 501-4755. Please cite FAR case 90-59.

## SUPPLEMENTARY INFORMATION:

## A. Regulatory Flexibility Act

The proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because most contracts awarded to small business are awarded on the basis of sealed bidding and no certified cost or pricing data is required. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected FAR subsection will also be considered in accordance with section 610 of the Act. Such comments must be submitted separately and cite 5 U.S.C. 601, *et seq.* (FAR case 90-59) in correspondence.

## B. Paperwork Reduction Act

The proposed rule does not impose recordkeeping, information collection requirements, or collection of information from offerors, contractors, or members of the public which differ from the requirements currently approved by OMB pursuant to 44 U.S.C. 3501, *et seq.*, under OMB Control Number 9000-0013.

## List of Subjects in 48 CFR Part 15

Government procurement;  
Subcontract pricing.

Dated: November 1, 1991.

Albert A. Vicchiolla,

Director, Office of Federal Acquisition Policy.

Therefore, it is proposed that 48 CFR part 15 be amended as set forth below:

PART 15—CONTRACTING BY  
NEGOTIATION

1. The authority citation for 48 CFR part 15 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

2. Section 15.806-1 is amended by adding paragraphs (e) and (f) to read as follows:

## 15.806-1 General.

(e) Whenever a prime contractor is required to submit subcontractor cost or pricing data, the contracting officer should consider requiring the prime contractor to include the following information in its proposal or quotation in addition to other information required by Table 15-2 instructions for the Standard Form (SF) 1411 at 15.804-6. The type and amount of such additional information should be determined only after giving due consideration to both the relative importance of the item(s) or service(s) and the dollar amount involved. Examples of such information are:

(1) Size classification (large or small business) of each source;

(2) Reasons for proposed method of subcontracting (whether competitive or other than competitive);

(3) Subcontract types contemplated or negotiated;

(4) Comparison with invoice prices of prior subcontracts;

(5) Organizational relationship of proposed subcontractor to offeror;

(6) Explanation of any changes from previous "make-or-buy" decisions;

(7) Description of the extent of subcontract supervision; and

(8) Statement as to whether fees for cost type subcontracts exceed the fee limitations at 15.903(d).

(f) If a prime contractor fails to provide the results of the analysis of a subcontract proposal, as required by 15.806-1(a)(2), or if the analysis is so deficient or untimely as to preclude an adequate Government analysis of the prime contractor's proposal, the contracting officer should require the prime contractor to provide an adequate analysis. If the prime contractor refuses, the contracting officer should consider:

(1) Reducing the profit objective; or

(2) Withholding award and referring the matter to higher management for resolution.

[FR Doc. 91-26886 Filed 11-6-91; 8:45 am]

BILLING CODE 6820-34-M



# FOODSTREET

Thursday  
November 7, 1991

## Part V

## Department of Housing and Urban Development

Office of Assistant Secretary for Public  
and Indian Housing

Public Housing Mixed Income New  
Communities Strategy (MINCS)  
Demonstration Program Guidelines and  
Request for Applications; Notice



# DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

## Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-91-3305; FR-3036-N-01]

### Public Housing Mixed Income New Communities Strategy (MINCS) Demonstration Program Guidelines and Request for Applications

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Notice of demonstration guidelines and request for applications.

**SUMMARY:** This Notice announces guidelines for the Public Housing Mixed Income New Communities Strategy (MINCS) Demonstration Program, authorized by section 522 of the National Affordable Housing Act (Pub. L. 101-625, approved November 28, 1990). The purpose of this demonstration is to test the effectiveness of promoting the revitalization of troubled urban communities through the provision of public housing in socioeconomically mixed settings combined with the innovative use of public housing operating subsidies to stimulate the development of new affordable housing in such communities. This Notice announces that, as required by section 552(d), HUD will carry out the demonstration program with respect to public housing for families administered by the Housing Authority of the City of Chicago, Illinois (CHA). In addition, section 522(d) authorizes HUD to carry out a nationwide competition to authorize MINCS demonstration programs at up to three additional public housing agencies.

**APPLICATION DUE DATE:** Applications must be received by May 5, 1992.

**ADDRESSES:** Applications for the MINCS Demonstration must be sent to the Office of Resident Initiatives, room 4112, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; Attention: Paul L. Fletcher.

**FOR FURTHER INFORMATION CONTACT:** Paul L. Fletcher, Office of Resident Initiatives, Department of Housing and Urban Development, room 4100, 451 Seventh Street SW., Washington, DC 20410; (202) 708-4214 (TDD (202) 708-0850). (These are not toll-free numbers.)

**SUPPLEMENTARY INFORMATION:** The information collection requirements contained in this rule have been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1980.

Pending approval of these collections of information by OMB and the assignment of an OMB control number, no person may be subjected to a penalty for failure to comply with these information collection requirements.

Public reporting burden for the collection of information requirements contained in this rule are estimated to include the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Information on the estimated public reporting burden is provided in this document under the heading, Other Matters. Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be sent by December 9, 1991, to the Department of Housing and Urban Development, Rules Docket Clerk, 451 Seventh Street SW., Washington, DC 20410; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

### Background

Section 522 of the Cranston-Gonzalez National Affordable Housing Act (Pub. L. 101-625, approved November 28, 1990) (the Act) creates the Public Housing Mixed Income New Communities Strategy Demonstration (MINCS) Program, a ten-year demonstration program to test the effectiveness of promoting the revitalization of troubled urban communities through the provision of public housing in socioeconomically mixed settings combined with the innovative use of public housing operating subsidies to stimulate the development of new affordable housing.

The intent of the program is to provide more socioeconomically mixed living situations than normally occur in public housing projects. To this end, HUD will permit participating public housing agencies (including Indian Housing Authorities and hereinafter referred to as "PHAs") to lease public housing units to low-income households not of very low income (hereinafter referred to simply as "low-income households"). It is intended that low-income households admitted into public housing projects under this program will pay rents sufficient to fully cover average PHA operating costs per unit. The funds thereby released are to be used to assist an at least equal number of very low-income families to reside in economically mixed newly constructed or renovated privately owned projects. Not more than 25 percent of the units in

these privately owned projects may be leased under this demonstration.

This Notice sets forth the guidelines under which the demonstration program will operate, and solicits applications from PHAs for a nationwide competition for authorization to implement a MINCS demonstration.

### Summary of Program Features

A maximum of four PHAs will be allowed to participate in the MINCS demonstration program. In addition to the Housing Authority of Chicago, a maximum of three PHAs will be selected by nationwide competition, as required by section 522(d) of the NAHA. All four PHAs will be subject to the threshold and performance criteria described in these Guidelines.

Under the MINCS demonstration program, HUD will permit participating PHAs to use public housing operating subsidies to underwrite the operating cost of newly developed or recently renovated privately-owned affordable housing units leased in accordance with these guidelines. Use of operating subsidy will be permitted through an amendment to the Annual Contributions Contract (ACC) with the PHA.

That portion of the newly constructed or rehabilitated units that are privately developed and owned, and leased under contract to the PHA for the term of the demonstration, will provide residences for very low-income families who voluntarily agree to participate in the MINCS demonstration. The very low-income families that are offered an opportunity to participate in the demonstration program must reside, or have been offered a unit, in public housing administered by the participating PHA. Participating families must enter into a one-year lease with the PHA, renewable upon expiration for a period not to exceed seven years, which may be further extended (as described in Section X).

In order to prepare participating very low-income families for successful transition to the private rental housing market and homeownership within a reasonable period of time, the PHA must assure that a comprehensive program of services, counseling, and incentives will be made available in conjunction with the privately developed and owned housing units provided under the MINCS demonstration program.

Participating families residing in the privately developed and owned housing units must voluntarily enter into a contract of participation with the PHA delineating the mutual obligations and benefits of both parties. The contract of participation will become a part of the



lease agreement between the participating family and the PHA.

To facilitate the establishment of socioeconomically mixed communities within existing public housing developments, the Secretary will authorize participating PHAs to lease an equivalent number of units in those projects to low-income families who are not very low-income families, notwithstanding the provisions of section 16(b) of the U.S. Housing Act of 1937 (1937 Act).

Low-income families must enter into a one-year lease with the PHA, renewable annually upon expiration for a period not to exceed seven years, except as described in Section X. The monthly rental charge for each low-income

family in public housing may not exceed the ceiling rent level approved by HUD for use by the PHA.

To ensure that there is no loss of public housing units, for the entire term of the demonstration the number of newly developed or renovated privately owned affordable housing units for which operating subsidy use is authorized may not be less than the number of public housing units that, notwithstanding the demonstration program, would have been assisted with the operating subsidy amounts. Operating subsidy will be determined in accordance with the Performance Funding System (PFS) (24 CFR part 990), the ACC, and these Guidelines (described in section V).

In order to test the revitalization impact of the demonstration on the troubled urban community, participating PHAs must define the specific geographic area of the demonstration program, which must be smaller than the total geographic area under the jurisdiction of the PHA.

#### Other Matters

The collection of information requirements contained in this Notice have been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501-3502). Those sections of the Guidelines determined by the Department to contain collection of information requirements and the reporting burden are as follows:

Description	No. of respondents	Responses per respondent	Total annual responses	Hrs per response	Total
Implementation Plan—Sec. VII	4	1	4	48	192
Annual Report—Sec. XIII	4	1	4	16	64
Semi-Annual Report—Sec. XIII	4	2	8	24	192
Application—Sec. XV	10	1	10	48	480
Total Burden					928

These Guidelines do not constitute a "major rule" as that term is defined in section 1(d) of the Executive Order on Federal Regulations issued by the President on February 17, 1981. An analysis of the Guidelines indicates that they would not (1) have an annual effect on the economy of \$100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In accordance with 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that these Guidelines would not have a significant economic impact on a substantial number of small entities because, under section 522(d) of the Act, the number of participating PHAs is limited to four.

The General Counsel, as the Designated Official under Executive Order 12806, The Family, has determined that the policies contained in these Guidelines may have potential for significant impact on family formation, maintenance, and general well-being, for some families. The public housing MINCS demonstration, by

providing supportive services, counseling and incentives, can be expected to increase the opportunities for very low-income families to become self-sufficient and gain economic independence. Since the impact on the family is considered beneficial, no further review is necessary.

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in these Guidelines do not have substantial, direct effects on States, on their political subdivisions, or on their relationship with the Federal Government, or on the distribution of power and responsibilities among the various levels of government. The Notice's major effects would be on individuals.

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, room 10276, 451 Seventh Street SW, Washington, DC 20410.

Accordingly, the Department adopts the following Guidelines for the Public Housing Mixed Income New Communities Strategy Demonstration Program Guidelines.

#### Public Housing Mixed Income New Communities Strategy (MINCS) Demonstration Guidelines

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## I. Introduction

These guidelines implement the Public Housing Mixed Income New Communities Strategy (MINCS), a ten-year demonstration program authorized by section 522 of the National Affordable Housing Act (Pub. L. 101-625, approved November 28, 1990). The purpose of the program is to demonstrate the effectiveness of promoting the revitalization of troubled urban communities through the

provision of public housing in socioeconomically mixed settings combined with the innovative use of public housing operating subsidies to stimulate the development of new affordable housing in such communities.

## II. Program Establishment

### A. General

PHAs that have submitted successful proposals and have been designated by HUD to participate may be eligible to establish and carry out a local Mixed Income New Communities Strategy (MINCS) demonstration program.

### B. Coordinating Committee

For a PHA to be eligible for designation or selection for participation in the MINCS demonstration program, the chief executive officer of each unit of general local government in which the PHA is located must appoint a coordinating committee. The coordinating committee must participate in the development of the implementation plan (described in Section VII); review, monitor, and make recommendations for improvements in activities under the demonstration program; and ensure the coordination and delivery of services under Section X.

### C. Occupancy Conditions

When the PHA commences the MINCS demonstration and for the entire term thereafter, equal numbers of public housing units for low-income families and privately-owned housing units for very low-income families, designated for demonstration use, must be available for occupancy by families participating in the demonstration.

### D. Incentives

A demonstration program must provide a comprehensive program of services (defined in Section III) and incentives (described in Section XI) for eligible families electing to participate in the program.

### E. Nondisplacement

No person who is a tenant of public housing during the term of the demonstration program may be displaced (permanent, involuntary move) as a result of the demonstration program. In addition to sanctions under the agreement, a violation of this policy may trigger a requirement to provide relocation assistance under the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (URA).

## III. Definitions

For the purpose of this program:

*Act* means the National Affordable Housing Act (Pub. L. 101-625, approved Nov. 28, 1990).

*Adjusted Income* means income as determined under 24 CFR part 913.

*Affordable housing* means units that allow low-income families to lease modest housing in the bottom half of the rental market without incurring a high rent burden while at the same time exercising some degree of "freedom of choice" in the selection of decent, safe, and sanitary rental housing in the PHA jurisdiction.

*Annual Contributions Contract (ACC)* means a contract (in the form prescribed by HUD) under which HUD agrees to provide financial assistance and the PHA agrees to comply with HUD requirements for the development and operation of a public housing development.

*Ceiling rent* means the monthly rent approved by HUD for use by the public housing agency as specified under section 3(a)(2)(A) of the U.S. Housing Act of 1937.

*Certification* means a written assertion based on supporting evidence to be kept available for inspection by the Secretary, the Inspector General, and the public, which assertion shall be deemed to be accurate for purposes of this Notice, unless the Secretary determines otherwise after inspecting the evidence and providing due notice and opportunity for comment.

*Contract of Participation* means a contract entered into between a "participating family" and a "participating public housing agency" in accordance with Section X of this Notice.

*Coordinating committee* means a local coordinating committee established by the chief executive officer of each unit of general local government in which a PHA is located, as described in Section VIII herein.

*Demonstration program* means the program established by the Secretary under Section 522 of the Act.

*Demonstration period* means the ten-year period beginning on the date of enactment (November 28, 1990) of the Act and ending upon the expiration of the 10-year period beginning on the date of the enactment of this Act.

*Earned income* includes, but is not exclusive to, income from wages, tips, salaries, other employee compensation, and any earnings from self-employment.

*Head of the family* means any adult member named on the lease that the family so designates. This designation may be changed upon written notification to the PHA by the family.



The head of family need not be a signatory to the lease.

*Low-income family* means a family whose income does not exceed 80 percent of the median income for the area, as determined by the Secretary with adjustments for smaller and larger families, except that the Secretary may establish income ceilings higher or lower than 80 percent of the median for the area on the basis of findings by the Secretary that such variations are necessary because of prevailing levels of construction costs or unusually high or low family incomes.

*Newly constructed private housing* means privately developed and owned housing that has been built but never occupied, or privately developed and owned housing for which the title has not been vested from the developer/builder to the homeowner/purchaser.

*Operating subsidy amounts* means assistance for public housing provided through the Performance Funding System under section 9 of the U.S. Housing Act of 1937.

*Participating family* means a family that is residing in newly constructed or rehabilitated housing units that are privately developed and owned and who has voluntarily entered into a contract of participation (defined in Section X) with the PHA.

*Participating PHA* means a public housing agency with respect to which the Secretary carries out the demonstration program under the Act.

*Privately Developed Housing Project* means any privately developed and owned housing leased by the PHA for this demonstration and specifically described in the Amended Annual Contributions Contract and in the PHA's Implementation Plan. Privately developed housing includes any of the following that were not developed, constructed, or rehabilitated with funds provided pursuant to section 5 of the U.S. Housing Act of 1937 and which otherwise meet the requirements of this Notice:

- (1) One or more contiguous buildings;
- (2) An area of contiguous row houses, or;
- (3) Scattered site buildings.

Such housing cannot be owned by a PHA, a PHA-owned or operated housing development corporation or non-profit identity-of-interest corporation, or an Economic Development Corporation with financial ties to the PHA.

*Public Housing Agency (PHA)*, *public housing*, and *project* have the meanings given such terms under section 3(b) of the U.S. Housing Act of 1937, including Indian Housing Authorities as defined in section 3(b)(11) of such Act.

*Rehabilitation* means the improvement of the condition of a property from deteriorated or substandard to good condition (see 24 CFR part 968). Rehabilitation may vary in degree from gutting and extensive reconstruction to the cure of substantial accumulation of deferred maintenance. Cosmetic improvements alone do not qualify as rehabilitation under this definition. Rehabilitation may also include renovation, alteration or remodeling for energy efficiency, the conversion or adaptation of structurally sound property to the design and condition required for use under these Guidelines, or the repair or replacement of major building systems or components in danger of failure.

*Resident Council (RC)*, *Resident Management Corporation (RMC)* and *Resident Organization (RO)* have the meaning given such terms in Subpart C of 24 CFR part 964 and 24 CFR 905.355.

*Secretary* means the Secretary of the U.S. Department of Housing and Urban Development.

*State* means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, and Indian tribes. An Indian tribe is any tribe, band, pueblo, group, community, or nation of Indians or Alaska Natives.

*Successful completion of the demonstration program* means that the participating family, at the end of the seven-year period or before, is able to move into private rental housing or homeownership.

*Supportive services* means those services and counseling that a PHA shall make available to a participating family in accordance with the contract of participation, and may include the following:

- (1) Remedial education;
- (2) Education for completion of high school;
- (3) Job training and preparation;
- (4) Child care;
- (5) Substance abuse treatment and counseling;
- (6) Training in homemaking skills and parenting;
- (7) Family counseling;
- (8) Financial counseling services emphasizing planning for homeownership, provided by local financial institutions under the Community Reinvestment Act of 1977, provided under section 106 of the Housing and Urban Development Act of 1968 or title IV of the U.S. Housing Act of 1937, as amended by the National

Affordable Housing Act (HOPE), or otherwise provided; and

(9) Any other services and resources appropriate to assist participating families to achieve economic independence and self-sufficiency.

*Troubled urban community* means a Community Development Block Grant (CDBG)—eligible city or urban county whose per capita funding exceeds by 20 percent the per capita average of all CDBG—eligible cities and urban communities.

*Unit of general local government* means any city, town, township, county, parish, village, or other general purpose political subdivision of a State.

*Very low-income family* means a Lower Income Family whose Annual Income does not exceed 50 percent of the median income for the area, as determined by HUD, with adjustments for smaller and larger families. HUD may establish income limits higher or lower than 50 percent of the median income for the area on the basis of its finding that such variations are necessary because of unusually high or low family incomes.

#### IV. Developing Private Housing

##### A. General

To stimulate the development of new affordable housing in troubled urban communities PHAs will be permitted innovative use of public housing operating subsidies. HUD will allow a reasonable amount of time, to be approved by the Secretary, for the privately-owned units to be ready for occupancy.

##### B. Determination of Development Location and Size

A participating PHA and the applicable unit of general local government must jointly determine, with approval of the legislative body of the local government:

- (1) the location of any newly constructed or rehabilitated housing to be utilized under the demonstration program carried out by the PHA, which location must meet the site and neighborhood standards of 24 CFR 941.202, and;
- (2) the number of units to be developed annually.

##### C. Size Limitation

The total number of newly constructed or rehabilitated units that may be used under this section in the demonstration program may not exceed—

- (1) 15 percent of the number of units administered by the agency for any



participating PHA with not more than 5,000 public housing units;

(2) 10 percent of the number of units administered by the agency for any participating PHA with more than 5,000 but not more than 25,000 units; and

(3) 4 percent of the number of units administered by the agency for any participating PHA with more than 25,000 units.

#### *D. Interagency Cooperation*

A participating PHA may seek the cooperation and receive assistance from State, county, and local governments and the private sector to develop housing for use under this section. Such assistance may include, but is not limited to—

(1) Donations of land and write-downs and discounts on land by local governments;

(2) Abatement of real estate taxes for specified periods by local, county, or State governments;

(3) Use of Community Development Block Grant funds or section 108 loan guarantee proceeds made available under title I of the Housing and Community Development Act of 1974, subject to any restrictions set forth in 24 CFR part 570;

(4) Low interest rate financing through Federal Home Loan Bank programs, State or Federal programs, and private lenders;

(5) Low-income housing tax credits from State and local governments;

(6) Mortgage revenue bonds from State or local governments; and

(7) Aid from utilities, including fuel assistance and favorable rate setting.

#### **V. Private Development Support and Occupancy Conditions**

##### *A. Use of Public Housing Operating Subsidies*

For purposes of the demonstration program, the Secretary will amend the Annual Contributions Contract (ACC) between the Secretary and each participating PHA to permit the PHA to utilize operating subsidy amounts allocated to the PHA in accordance with the Performance Funding System (PFS), as adjusted by the ACC amendment and these Guidelines, with respect to newly constructed or rehabilitated housing units that are privately developed and owned, and leased to the PHA in accordance with the provisions of these Guidelines.

The PHA must ensure that, in budgeting the amount of the operating subsidy under the contract, it retains sufficient funds to cover the operation costs of its PHA-owned inventory, along with any costs related to the PHA's

commitment to the MINCS demonstration program, including the establishment and maintenance of escrow savings accounts.

##### *B. Performance Funding System Calculations*

Except as outlined below, the calculation of Performance Funding System eligibility for a PHA in the demonstration program will be in accordance with the PFS regulations at 24 CFR part 990. The PFS calculation will be based on the characteristics, including utility costs, of the PHA-owned units. Under the PFS, average monthly dwelling rental income is estimated based on the average dwelling rental charge for all PHA units.

*Exception.* Participating PHAs in the MINCS demonstration must include the rents charged each participating family under contract and residing in the private development in calculating the average monthly dwelling rental income. In each case where the income of a participating family is included in the calculation of average rent, the rental income of one low-income family residing in a public housing unit under the provisions of Section XII will be excluded from the calculation.

The average monthly dwelling income will not be adjusted to reflect any PHA contributions to an escrow savings account, but should be adjusted to exclude any rent increases charged because of increases in the earned income of the family which are to be deposited into the family's escrow savings account. The escrow accounts for participating families will be excluded from the calculations of investment income for PFS purposes.

##### *C. Unit Limitation*

The PHA must comply with the following unit limitations:

(1) *Private Units.* Not more than 25 percent of the units in each privately developed housing project under the demonstration program may be leased by a PHA pursuant to a lease contract under subsection (D).

(2) *Public Units.* The number of units under subsection (D) may not be less than the number of public housing units that, notwithstanding the demonstration program, would have been assisted with the operating subsidy amounts made available under such contract.

##### *D. PHA/Private Owner Lease*

The participating PHA must enter into a lease contract with the private owner specifying the number of privately developed housing units to be covered by the demonstration for the demonstration duration. The PHA must

account separately for all funds provided to private owners. This will allow HUD to evaluate the effectiveness of the program.

##### *E. PHA/Private Owner Lease Terms*

Operating subsidy amounts for each privately developed unit will be provided for the operation of housing under subsection (A) pursuant to a lease agreement between the owner of the housing and the PHA, which shall specify—

(1) The number of units to be leased exclusively to the PHA for the term of the demonstration program, subject only to the availability of amounts under subsection (A) or other funds for such purposes;

(2) PHA payments to the private developer should be made on a monthly basis reflecting the number of units under lease;

(3) The private owner will be responsible for routine and extraordinary maintenance for the units in each privately developed housing project being leased by a PHA; and

(4) The requirements under Section VI (C).

##### *F. Transfer of Operating Subsidy Amounts*

Operating subsidy amounts may be provided for one unit of the newly constructed or rehabilitated privately developed and owned property only after the execution of a lease under Section XII for one corresponding public housing unit.

##### *G. Occupancy*

Occupancy terms and conditions for units leased by a participating PHA for use under the demonstration program will be solely at the discretion of the PHA, as provided under Section IX, consistent with the provisions of title VI of the Civil Rights Act of 1964 and related regulations.

##### *H. Rental Terms*

The rental charge for the total number of units leased by the PHA under the demonstration may be determined jointly by the PHA and the private development owner.

#### **VI. Public Housing Units**

##### *A. General*

Over the term of the demonstration, the demonstration may be applied to not more than 15 percent (specific size limitations are provided in Section IV) of the total number of public housing units for families administered by each participating PHA.



*B. Limitations on Low-income Residents*

Except as noted below, not more than 25 percent of the units in each public housing project in which units are utilized under the demonstration program may be occupied by low-income families who are not very low-income families.

*Exception.* Upon determining that a PHA has a special need, the Secretary may provide for not more than 50 percent of the units in a public housing project utilized under the demonstration program to be occupied by low-income families who are not very low-income. Such special need may include the need to ensure the successful revitalization of troubled public housing through establishing a socioeconomically mixed resident population.

*C. Vacancy*

If, at any time, a participating PHA is unable to rent a public housing unit made available under Section XII and the unit has been vacant for a period of six months, the PHA may cancel a PHA/participating family lease for one unit of housing provided in Section IV and withhold any further operating subsidy payments associated with the privately owned unit (as described in Section V). As required in Section V, such public housing unit must be removed from participation in the demonstration program and made generally available for occupancy as provided under the U.S. Housing Act of 1937. The PHA must provide the participating family residing in the housing unit provided under Section IV (from which operating subsidy amounts have been removed) with assistance under Section 8(b) of the U.S. Housing Act of 1937, subject to the availability of such assistance pursuant to appropriations acts and notwithstanding any preferences for such assistance under Section 8(d)(1)(A)(i) of the 1937 Act, and permit the family to remain in the unit. If Section 8 assistance is not available, the PHA must offer the participating family a unit in public housing. To the extent possible, the PHA must maintain the terms and conditions of the contract of participation with the affected very low-income family.

*D. Ceiling Rents*

For the entire term of the demonstration, the PHA must have in place an approved ceiling rent policy for public housing units that are designated for use under the MINCS demonstration. The PHA may apply to HUD for approval of ceiling rents as outlined in the March 15, 1989 Federal Register Notices at 54 FR 10730 and 10733.

**VII. Implementation Plan***A. General*

Each PHA, in conjunction with the coordinating committee, must develop an implementation plan that outlines the specific goals of the program and details how the MINCS demonstration will be carried out in its local jurisdiction.

*B. Development of Implementation Plan*

The plan must be developed by the program coordinating committee as detailed in Section VIII.

*C. Submission*

The final implementation plan must be submitted to HUD for approval within 90 days after the selection of the PHA for participation in the demonstration program.

*D. Changes to the Implementation Plan*

A PHA must request HUD approval of any significant changes to its plan.

*E. On-Site Facilities*

Each PHA may, subject to the approval of HUD, make available and utilize common areas or unoccupied public housing units in public housing projects administered by the PHA for the provision of supportive services under the demonstration program. Upon approval of the required waiver, the use of the facilities of a PHA under this section will not affect its eligibility to receive operating subsidy under section 9 of the U.S. Housing Act of 1937. The PHA may apply for a waiver to receive operating subsidy for a non-dwelling unit as outlined in PIH Notice 90-39, dated August 24, 1990.

*F. Implementation Plan Contents*

An implementation plan must contain, at a minimum:

- (1) The specific geographic area of the demonstration program, which must be smaller than the total geographic area covered by the PHA, including a description of the size, location, age, and other characteristics (including racial and ethnic data) of the public housing site or sites that will be selected as a demonstration location;
- (2) A description of the anticipated size, location, and other characteristics (including racial and ethnic data), as well as a financial pro-forma of any newly constructed privately developed housing site or sites that will be selected as a demonstration location.
- (3) A description of the size, location, and other characteristics (including racial and ethnic data), as well as a financial pro-forma of any recently rehabilitated privately developed

housing site or sites that will be selected as a demonstration location.

(4) A financial plan indicating how the requirements of Section 406 of the ACC will be met with reference to the maintenance and operation of the units in the public housing community occupied by selected low-income families, taking into consideration the diversion of available operating subsidies to pay rents for the privately owned units in accordance with the provisions of Section 522 of the Act.

(5) A description of the number of eligible very low-income families who can reasonably be expected to volunteer to participate, and the anticipated Federal, State, local, and private supportive services that will be available to assist these families, and how the supportive services will be delivered;

(6) A description of how residents of public housing have been involved in the MINCS application process, and what involvement residents will have in MINCS' implementation;

(7) A description of the supportive services that are available, or will be made available, to public housing residents at the MINCS public housing site, and how the supportive services will be delivered;

(8) A description of the process by which the eligible very low-income families will be selected and the process by which the continued participation requirements will be monitored and enforced;

(9) A description of the number, and race and ethnicity, of eligible low-income families who can reasonably be expected to volunteer to participate and a description of the process by which these eligible applicants will be selected;

(10) A description of the anticipated staffing patterns over the life-time of the demonstration and a detailed plan outlining the maintenance of the required effort over the ten-year period; and

(11) A timetable for implementation of all phases of the local demonstration program.

**VIII. Program Coordinating Committee***A. General*

For a PHA to be eligible for designation or selection for participation in the demonstration program, the chief executive officer of each unit of general local government in which the PHA is located must appoint a coordinating committee under this section. The coordinating committee must participate in developing a plan for implementing



the demonstration program, review, monitor, and make recommendations for improvements in activities under the demonstration program, and ensure the coordination and delivery of services under Section X(C).

#### *B. Membership*

Each coordinating committee must be composed of 12 members, which must include, but is not limited to, the following individuals:

- (1) A representative of the chief executive officer of the applicable unit of general local government;
- (2) A representative of the participating PHA;
- (3) A representative of the Regional Administrator of the U.S. Department of Housing and Urban Development;
- (4) A representative of the Resident Management Corporation (RMC) (if such a resident entity exists), Resident Council (RC) or Resident Organization (RO) associated with the MINCS public housing demonstration site; or, if no RMC, RC, or RO exists at the site, a representative from any PHA-wide resident association.

(5) Not less than one individual affiliated with a local agency that administers programs in one of the following areas: health, human services, substance abuse, education, economic and business development, law enforcement, and housing.

(6) A representative from among local businesses engaged in housing and real estate, except one who is:

- (a) Involved in the development, construction or operation of the newly constructed or rehabilitated privately developed and owned units under Section IV, or;

(b) Providing services under contract to the participating PHA.

(7) A representative from among business engaged in real estate financing, except one who is:

- (a) Involved in the development, construction or operation of the newly constructed or rehabilitated privately developed and owned units under Section IV, or;

(b) Providing services under contract to the participating PHA.

#### *C. Social Service Committee*

Each coordinating committee established under this section must establish a subcommittee on social services, which must, before any action is taken under Section V with respect to the demonstration program as carried out by the applicable PHA, identify the specific services that are required to successfully carry out the demonstration program.

### **IX. Participation of Very Low-Income Families**

#### *A. Eligibility*

Eligibility for selection for the MINCS demonstration program is limited to very low-income families that reside, or have been offered a unit, in public housing administered by the PHA and that enter into a voluntary contract of participation under Section X.

#### *B. Selection*

A PHA must establish written selection criteria for families volunteering to reside in the newly constructed or rehabilitated units that are privately developed and owned. The criteria must be based on factors that may reasonably be expected to predict the family's ability to successfully complete the requirements of the demonstration program and must be submitted to HUD for review. The criteria must include—

- (1) The status and history of employment of family members;
- (2) Enrollment of the children in the family in an educational program;
- (3) Maintenance by the family of the family's previous dwelling;
- (4) Ability of adult family members to complete training for long-term employment;
- (5) The existence and seriousness of any criminal records of family members; and
- (6) The status and history of substance abuse of family members.

#### *C. Rental Terms*

The rental charge for each unit under the contract must be the amount equal to 30 percent of the adjusted income of the resident family, except that the rental charge at any time during the demonstration period may not exceed the ceiling rent approved for the PHA.

#### *D. Sublease*

A participating PHA must enter into a sublease with each very low-income family occupying a privately owned unit made available under Section IV. The term of each sublease must be one year, renewable upon expiration for a period not to exceed seven years, except as described in Section X.

#### *E. Utilities*

For the entire term of the demonstration, all utilities must be included in the tenant's rent. To assure continued affordability, PHAs should, with the aid of utility companies and others, counsel occupants on maintaining energy efficiency.

### *F. Continued Participation*

Continued residency of families in the newly constructed or rehabilitated units that are privately developed and owned is to be contingent upon compliance with standards established by the participating PHA, which must include—

(1) Except as provided below, the head of the family being employed on a full-time basis for the entire term of residency.

*Exception.* If the head of the family becomes involuntarily unemployed, prior to taking any action, the PHA and the family must meet to discuss what steps the PHA will take to alter the contract of participation.

(2) All members of the family remaining drug-free;

(3) No member of the family engaging in any criminal activity;

(4) Each child in the family remaining in an educational program until receipt of a high school diploma or the equivalent thereof;

(5) All members of the family either in school, in a training program or working, except for a show of good cause; such as, pregnancy, loss of child care, illness, etc.; and

(6) Family members participating in the support services and counseling as noted in Section X.

### **X. Contract of Participation**

#### *A. General*

A participating PHA must enter into a contract with each very low-income family that will reside in a unit of privately developed and owned housing leased to the PHA in accordance with Section V. The contract may be revised at any time with the mutual agreement of both parties.

(1) Each family must meet the criteria established in accordance with Section IX and must enter into the contract voluntarily.

(2) The contract must be made part of the lease executed between the family and the PHA for such unit. The lease must be for a term of one year and must be renewable upon expiration for a period not to exceed seven years, except as provided under subsection F.

(3) The contract must set forth in detail the provisions of the demonstration program that apply to the participating family, and must specify the resources to be made available to the participating family and the responsibilities of the participating family and the PHA under the program.



**B. Obligations**

The contract must specify in detail the mutual nature of the obligations of the participating family and the participating PHA.

(1) The contract must specify the actions the participating family will take to fulfill its contract obligations along with the services and resources to be made available to the family.

(2) The participating PHA must ensure the availability of supportive services and the provision of counseling to assist family members in gaining, advancing in, and retaining employment.

(3) The contract must include well-defined time lines and benchmarks for progress for both the family and the PHA. Thus, the PHA/participating family contract will be viewed as the basic tool for outlining the mutual responsibilities, expectations, and specific tasks of the participating families and the PHA.

**C. Supportive Services Provision**

For the entire term of residency of a participating family in the newly constructed or rehabilitated units that are privately developed and owned, the PHA must ensure the availability of supportive services (as defined in Section III) and counseling to the family. The PHA must provide for such services and counseling through its own resources and through coordination with Federal, State, and local agencies, community-based organizations, and private individuals and entities.

**D. Counseling**

The PHA must, during the term of the contract, including any extension of the term, provide counseling for participating families with respect to affordable rental and homeownership opportunities in the private housing market and on individuals' rights under the Fair Housing Act, and money management counseling.

**E. Incentives**

The contract should set out the terms and conditions governing the family's individual escrow account, the treatment of earned income, and rental increases in accordance with Section XI.

**F. Extension**

The PHA must, in writing, extend the term of the contract for any participating family that requests an extension of the seven-year period, not to exceed the demonstration period—

(1) Because the family is not prepared to enter a program for homeownership or to secure any other form of private housing; or

(2) For other good cause.

As used in this subsection, "good cause" means circumstances beyond the control of the family such as a serious illness, loss of employment, the family's inability to complete any of the supportive services under its contract of participation because of unanticipated delays in the delivery of the service, or housing market conditions that make it difficult or impossible for the family to obtain private housing as either a renter or homeowner.

**G. Incompletion**

Except as provided below, if a participating family is unable to successfully fulfill the requirements under the demonstration program, the PHA must offer the family a comparable public housing unit in a project administered by the PHA (notwithstanding any preference for residency in public housing under section 6(c)(4)(A)(i) of the U.S. Housing Act of 1937), or assistance under section 8 of such Act (subject to availability of amounts provided under appropriations Acts and notwithstanding any preference for such assistance under section 8(d)(1)(A)(i) of such Act). Incompletion includes cancellation/termination of the demonstration program by either HUD or the participating PHA.

**Exception.** Subsection (G) does not apply to any participating family that has committed serious or repeated violations of the terms and conditions of the lease or applicable Federal, State, or local law, or that has been exempted from such requirement by the PHA for other good cause. Further, participants who violate current public and Indian housing rules or regulations will be subject to appropriate sanctions provided for in existing PIH rules, regulations, and procedures.

**H. Termination and Cancellation**

The contract must outline the conditions for termination and/or cancellation by either one or both parties.

(1) A participating family's contract may be terminated for serious or repeated violations of the terms and conditions of the lease, or of applicable Federal, State, or local law.

(2) A participating family may, at any time by giving written notice to the PHA, terminate its participation in the demonstration program, indicating its desire to vacate the privately developed and owned unit.

**XI. Incentives for Very Low-Income Families****A. Rent Increases**

During the residency of the participating families in the privately developed and owned housing, rent increases must be calculated as follows:

(1) For the one-year period beginning when the family takes up residency, the amount of rent charged the participating family may not be increased on the basis of any increase in the earned income (as defined in Section III) of the family, until such earned income exceeds 80 percent of the median family income for the area, as determined by HUD, with adjustments for family size.

(2) For the second year of the family's residency, when computing rent, the PHA will disregard half of the difference between the participating family's earned income for that year and its earned income at the time it signed a contract of participation. If the family's income exceeds 80 percent of the median family income for the area, as determined by HUD with adjustments by family size, the family will pay 30 percent of the family's adjusted income or the ceiling rent, whichever is lower.

(3) After the second year, the family's rent must be increased either up to an amount equal to 30 percent of the family's adjusted income or the ceiling rent, whichever is the lower amount.

(4) At any time, rent may be adjusted on the basis of changes in unearned income.

**B. Escrow Savings Account**

Each participating PHA must establish and maintain for each participating family an interest-bearing escrow savings account. The PHA must hold the escrow account in the family's name. Separate accounting must be maintained of the escrow set up for the very low income families.

(1) **Periodic deposits.** For the entire term of a participating family's residency in newly constructed or renovated privately owned units, the PHA must deposit in the account established for the family under subsection (B) a percentage of the monthly rent charged the family.

(a) The PHA is required to deposit a minimum of five percent per month of the rental charge in the escrow account. The actual percentage must be established in the contract of participation under Section X.

(b) Any rent increases charged because of increases in the earned income of the family must also be deposited by the PHA into the escrow account.



(2) *Withdrawal and Assignment.* The participating family will have no right to assign, withdraw, or in any way dispose of the funds in its escrow account, except as provided in this section.

(3) *Access to amounts.* Except as provided below, a participating family may withdraw amounts in the family's escrow account only upon successful completion of participation in the demonstration program. After successful completion of participation, escrow savings may be used for purchase of a home, for contribution toward college tuition, or other good causes as determined by the PHA.

*Exception.* Paragraph (3) does not apply to any family whose participation has been terminated or cancelled as referenced by Section X (H). Such actions constitute forfeiture of the escrow saving account to the PHA. Forfeited escrow account funds must be treated by the PHA as program receipts and used in accordance with HUD regulations governing the use of program receipts.

#### C. Treatment of Increased Income

Any increase in the earned income of a participating family during residency in the newly constructed or renovated privately owned units may not be considered as income or a resource for the purpose of the family for benefits, or amount of benefits payable to the family, under any other Federal law, unless the income of the family equals or exceeds 80 percent of the median income of the area (as determined by the Secretary, with adjustments for smaller and larger families).

### XII. Participation of Low-Income Families

#### A. Selection

Participating PHAs may lease units in existing public housing projects to low-income families who are not very low-income families, notwithstanding the provisions of section 16(b) of the U.S. Housing Act of 1937.

#### B. Eligibility

To be eligible for selection to lease units in existing public housing projects under the MINCS demonstration program, families must be low income.

#### C. Rental Terms

The rent charged any family occupying a unit made available under this section may not, at any time during the demonstration period, exceed the ceiling rent level determined by the PHA.

#### D. Lease

A participating PHA must enter into a lease with each low income family occupying a public housing unit made available under this section. The term of each lease will be one year. Each lease must be renewable upon expiration for a period not to exceed seven years, unless extended as described under this section.

#### E. Extension

The PHA must, in writing, extend the term of the lease for any low-income family that requests an extension of the seven-year period, not to exceed the demonstration period—

(1) Because the family is not prepared to enter a program for homeownership or to secure any other form of private housing; or

(2) For other good cause.

As used in this subsection, "good cause" means circumstances beyond the control of the family such as a serious illness, loss of employment, or housing market conditions that make it difficult or impossible for the family to obtain private housing as either a renter or homeowner.

### XIII. Reports

#### A. General

Each PHA must submit annual and quarterly reports to HUD in such form and timing as HUD may require. These reports must contain such information as:

(1) A description of the activities necessary to obtain privately developed and owned housing for the demonstration program;

(2) A description of the program's activities in promoting revitalization of the targeted community through the provision of public housing in socioeconomically mixed settings;

(3) A description of the race and ethnicity of families who applied to and participated in the program;

(4) A description of the program's activities in combining the innovative use of public housing operating subsidies with affordable private housing to stimulate the development of new affordable housing in the targeted communities;

(5) A description of the program's activities in coordinating resources of the community to assist families to achieve economic independence and self-sufficiency;

(6) A description or itemization of the supportive services available to participating families, and any other information that HUD may request from its review of the PHA's implementation plan; and

(7) Any recommendations of the PHA or the appropriate local program coordinating committee for legislative or administrative action that would improve the self-sufficiency program and ensure the effectiveness of the program.

#### B. Congressional Reports

At the end of the first year of the demonstration, HUD will reassess the need for quarterly reports, and may adjust the frequency as appropriate. HUD will submit to the Congress interim reports addressing the effectiveness of the demonstration program and information regarding other items as required.

#### C. HUD Evaluation

HUD may perform a thorough, long-term evaluation of the public housing MINCS demonstration program. To help assure the quality of that evaluation, each PHA must submit a certification with the application agreeing to cooperate with and provide requested data to the entity responsible for the program evaluation, if requested to do so by HUD.

#### D. Failure to Comply with Guidelines

Failure to comply with these guidelines may result in termination of participation of the PHA in the demonstration. If HUD discovers that a violation has occurred, the PHA will be given 180 days after notification by HUD of the violation to make corrections. HUD will meet with the PHA during the first 30 days after the notification to develop a plan for resolving any violations or deficiencies or, if necessary and appropriate, a plan to begin moving the very low income residents from the privately owned units into public housing or other suitable housing.

### XIV. Other Federal Requirements

To the extent applicable, the participating PHAs must comply with the following Federal requirements:

#### A. Nondiscrimination and Equal Opportunity

1. The requirements of the Fair Housing Act of 1968 (42 U.S.C. 3600-19) and implementing regulations at 24 CFR part 100 (and for new construction only, the design and construction standards of the Fair Housing Act and HUD's implementing regulations at 24 CFR 100.205); Executive Order 11063 (Equal Opportunity in Housing) and implementing regulations at 24 CFR part 107; and Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d-2000d-4)



(Nondiscrimination in Federally Assisted Programs) and implementing regulations at 24 CFR Part 1.

2. The Indian Civil Rights Act (title II of the Civil Rights Act of 1968, 25 U.S.C. 1301-1303) provides, among other things, that "no Indian tribe in exercising powers of self-government shall \* \* \* deny to any person within its jurisdiction the equal protection of its laws or deprive any person of liberty or property without due process of law." The Indian Civil Rights Act applies to any tribe, band, or other group of Indians subject to the jurisdiction of the United States in the exercise of recognized powers of self-government. The ICRA is applicable in all cases where an IHA has been established by exercise of tribal powers of self-government.

3. The prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975 (42 U.S.C. 6101-07) and implementing regulations at 24 CFR part 146, and the prohibitions against discrimination against handicapped individuals under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and implementing regulations at 24 CFR part 8.

4. The requirements of Executive Order 11246 (Equal Employment Opportunity) and the regulations issued under the Order at 41 CFR chapter 60.

5. The requirements of section 3 of the Housing and Urban Development Act of 1968, 12 U.S.C. 1701u (Employment Opportunities for Lower Income Persons in Connection With Assisted Projects).

6. The requirements of Executive Orders 11625, 12432, and 12138. Consistent with HUD's responsibilities under these Orders, participating PHAs must make efforts to encourage the use of business enterprises owned by minorities and women in connection with demonstration activities.

#### *B. Debarred or Suspended Contractors*

Participating PHAs are subject to the provisions of 24 CFR part 24 relating to the employment, engagement of services, awarding of contracts, or funding of any contractors or subcontractors during any period of debarment, suspension, or placement in ineligibility status.

#### *C. Conflict of Interest*

In addition to the conflict of interest requirements in 24 CFR part 85, no person who is an employee, agent, consultant, officer, or elected or appointed official of the participating PHA and who exercises or has exercised any functions or responsibilities with respect to assisted activities; or who is in a position to

participate in a decisionmaking process or gain inside information with regard to such activities may obtain a personal or financial interest or benefit from the activity, or have an interest in any contract, subcontract, or agreement with respect thereto, or the proceeds thereunder, either for him or herself or for those with whom he or she has a family or business ties, during his or her tenure, or for one year thereafter.

#### *D. Drug-Free Workplace*

Participating PHAs must certify that they will provide a drug-free workplace, in accordance with the Drug-Free Workplace Act of 1988, as implemented at 24 CFR part 24, subpart F.

#### *E. Anti-Lobbying Certification*

Section 319 of Public Law 101-121 prohibits recipients of Federal contracts, grants, and loans from using appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government. A common rule governing the restrictions on lobbying was published as an interim rule on February 28, 1990 (55 FR 6736) and supplemented by a Notice published June 15, 1990 (55 FR 24540). The rule requires applicants, recipients, and subrecipients of assistance exceeding \$100,000 to certify that no Federal funds have been or will be spent on lobbying activities in connection with the assistance. The rule also requires disclosures from applicants, recipients, and subrecipients if nonappropriated funds have been spent or committed for lobbying activities if those activities would be prohibited if paid with appropriated funds. The law provides substantial monetary penalties for failure to file the required certification or disclosure.

#### *F. Displacement, Relocation, and Real Property Acquisition*

The requirements of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (URA), implementing regulations at 49 CFR part 24, and HUD Handbook 1378, Tenant Assistance, Relocation and Real Property Acquisition. The participating PHAs must certify compliance with these provisions before HUD will approve the application.

#### *G. Environment*

Before approval, all projects are subject to environmental review by HUD under the National Environmental Policy Act, as implemented at 24 CFR part 50, and other Federal authorities listed at 24 CFR 50.4.

#### **XV. Application Requirements**

All applications must contain at least the following information, in such form as HUD may require:

1. A description of the PHA's past experience in assisting very low-income families to move toward economic self-sufficiency and homeownership, and other relevant experience, such as the ability to design and implement new programs.

2. Certification that the proposed MINCS demonstration site or sites is located in a geographic area that conforms with the definition of a troubled urban community.

3. A description of the specific geographic area of the demonstration program, which must be smaller than the total geographic area under the jurisdiction of the PHA, including a description of the size, location, age, and other characteristics (including racial and ethnic data) of the public housing site or sites that will be selected as a demonstration location.

4. A description of the anticipated size, location, and other characteristics (including racial and ethnic data), as well as a financial pro-forma of any newly constructed privately developed housing site or sites that will be selected as a demonstration location.

5. A description of the size, location, and other characteristics (including racial and ethnic data), as well as a financial pro-forma of any recently rehabilitated privately developed housing site or sites that will be selected as a demonstration location.

6. A detailed financial plan indicating how the requirements of Section 406 of the ACC will be met with reference to the maintenance and operation of the units in the public housing community occupied by selected low-income families, taking into consideration the diversion of available operating subsidies to pay rents for the privately owned units in accordance with the provisions of section 522 of the Act.

7. A description of how residents of public housing have been involved in the MINCS application process, and what involvement residents will have in MINCS' implementation;

8. A description of the supportive services that are available, or will be made available, to public housing residents at the MINCS public housing site.

9. A description of the number of eligible very low-income families who can reasonably be expected to volunteer to participate and their supportive service needs. This description must include:



a. An estimate of the kind of supportive service needs expected among the very low-income families to be served and the anticipated Federal, State, local, and private supportive service resources that will be available to assist these families.

b. An estimate of the cost of incentives required by Section XI of these guidelines and the source of the resources to cover these anticipated expenditures.

10. A description of the activities and supportive services to be provided and how they will be delivered by both public and private resources to participating families.

11. A plan for coordinating the provision of private housing for very low-income families with the required supportive services, as well as a description for the on-going monitoring of that plan.

12. A description of the process by which the eligible very low-income families will be selected and the process by which the continued participation requirements will be monitored and enforced.

13. A description of the number of eligible low-income families who can reasonably be expected to volunteer to participate, and a description of the process by which these eligible applicants will be identified, contacted, and selected.

14. A description of the anticipated staffing patterns over the life-time of the demonstration and a detailed plan outlining the maintenance of the required effort over the ten year period.

15. A timetable for implementation of all phases of the MINCS demonstration program.

16. Any additional information stipulated in the application package.

#### **XVI. Application Processing and Selection**

##### *A. Review of Applications*

Each application submitted by a PHA that meets the application requirements in Section XVI will be screened for completeness and technical deficiencies prior to rating and ranking.

During the screening process, if HUD determines that an application has technical deficiencies involving items that are not necessary for HUD's evaluation and ranking, the PHA will be given 14 calendar days from written notification to correct the deficiencies. The purpose of this process is to assist applicants in submitting ratable proposals and not to provide for

applications to be substantively improved once the application has been submitted.

All screened applications will be reviewed by a Headquarters panel. Field Office staff will also review all applications. This review will cover at least the management capacity of the PHA to administer the MINCS demonstration and prior experience in administering and/or coordinating economic self-sufficiency and homeownership programs. Field Office recommendations will be submitted to HUD Headquarters.

Final rating and ranking of the applications will be performed in Washington, DC.

##### *B. Selection Rating Criteria*

The selection rating criteria have a total value of 100 points, allocated as follows:

1. The demonstrated ability of the applicant to develop and operate the proposed program of coordinated services and incentives to very low-income families residing in privately developed and owned housing in an efficient and effective manner, including the applicant's contract monitoring capability, and prior experience in promoting economic self-sufficiency initiatives for its residents. (MAXIMUM POINTS: 25).

2. The quality of the implementation plan based upon the extent to which the information provided by the applicant is accurate and complete; the extent to which the applicant's strategy for expanding the number of affordable housing units in the community is realistic and attainable as evidenced by the degree to which development incentives are in place and the developer is under contract or identified; and the level of commitment of supportive service resources to assist very low-income families toward economic self-sufficiency and homeownership. (MAXIMUM POINTS: 25).

3. The need for a program providing housing assistance, supportive services, and economic incentives for very low-income families in the geographic area to be served. The lack of affordable private housing and the nature of activities undertaken to alleviate economic distress in the proposed MINCS geographic area. (MAXIMUM POINTS: 20).

4. The attractiveness of the facilities at the proposed public housing site or sites, the service amenities available on-

site and in the surrounding neighborhood and community. (MAXIMUM POINTS: 10).

5. The extent to which the PHA has incorporated RMC, RC, RO, or other resident involvement in the development of the application package; the extent to which resident entities will be involved in the PHA's implementation plan and on-going monitoring activities; and the extent to which an array of supportive services are available, or will be made available, to public housing residents at the MINCS public housing site or sites. (MAXIMUM POINTS: 10).

6. The extent to which non-PHA resources are committed to playing an active role in the supportive services program as demonstrated by letters of commitment. (MAXIMUM POINTS: 10)

##### *C. Final Selection*

All applicants will be rank-ordered by score.

#### **XVII. Announcement of Selection and Designation**

The Secretary will announce the selection and designation of PHAs to operate a MINCS demonstration. PHAs selected to participate in the MINCS demonstration will receive written notification of what PHA actions may be necessary to be designated to operate a MINCS demonstration, in such manner and in such time-frame that HUD may require.

HUD will also notify all non-selected applicants in writing.

#### **XVIII. Waiver Authority**

The Assistant Secretary for Public and Indian Housing may waive any provision of these Guidelines that is not required by law, upon a determination of good cause. This authority may not be redelegated by the Assistant Secretary for Public and Indian Housing. Each waiver will be in writing, supported by documentation of the pertinent facts and grounds, and signed by the Assistant Secretary. HUD will publish a **Federal Register** notice informing the public of all waivers granted and containing all relevant information concerning the waivers.

Dated: November 1, 1991.

Joseph G. Schiff,  
Assistant Secretary for Public and Indian Housing.

[FR Doc. 91-26963 Filed 11-6-91; 8:45 am]

BILLING CODE 4210-33-M



# great report

Thursday  
November 7, 1991

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## Part VI

## Department of the Interior

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### Bureau of Indian Affairs

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**Amah Band of Ohlone/Coastanoan  
Indians; Receipt of Petition for Federal  
Acknowledgment of Existence as an  
Indian Tribe; Notice**



**DEPARTMENT OF THE INTERIOR****Bureau of Indian Affairs****Amah Band of Ohlone/Coastanoan Indians; Receipt Of Petition For Federal Acknowledgment Of Existence As An Indian Tribe**

This is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

Pursuant to 25 CFR 83.8(a) (formerly 25 CFR 54.8(a)) notice is hereby given that the Amah Band of Ohlone/Coastanoan Indians, c/o Irene Zwierlein, 789 Canada Road, Woodside, California 94062 has filed a petition for acknowledgment by the Secretary of the

Interior that the group exists as an Indian tribe. The petition was received by the Bureau of Indian Affairs (BIA) on September 18, 1990, and was signed by members of the group's governing body.

This is a notice of receipt of petition and does not constitute notice that the petition is under active consideration. Notice of active consideration will be sent by mail to the petitioner and other interested parties at the appropriate time.

Under § 83.8(d) (formerly 54.8(d)) of the Federal regulations, interested parties may submit factual and/or legal arguments in support of or in opposition to the group's petition. Any information submitted will be made available on the same basis as other information in the

BIA's file. Such submissions will be provided to the petitioner upon receipt by the BIA. The petitioner will be provided an opportunity to respond to such submissions prior to a final determination regarding the petitioner's status.

The petition may be examined by appointment in the Department of the Interior, Bureau of Indian Affairs, Branch of Acknowledgment and Research, room 1362-MIB, 1849 C Street, NW., Washington, DC 20240, Phone: (202) 208-3592.

Eddie F. Brown,

*Assistant Secretary—Indian Affairs.*

[FR Doc. 91-26890 Filed 11-6-91; 8:45 am]

BILLING CODE 4310-02-M



# Federal Register

Thursday  
November 7, 1991

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## Part VII

### Department of Education

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#### 34 CFR Part 318

**Training Personnel for Education of  
Individuals With Disabilities; Application  
for Awards; Final Regulations and Notice**



## DEPARTMENT OF EDUCATION

## 34 CFR Part 318

RIN 1820-AA95

## Training Personnel for the Education of Individuals With Disabilities—Grants for Personnel Training

AGENCY: Department of Education.

ACTION: Final regulations.

**SUMMARY:** The Secretary amends regulations for the Training Personnel for the Education of Individuals with Disabilities program authority as reauthorized in the Education of the Handicapped Act Amendments of 1990. The regulations conform existing regulations to statutory provisions enacted in the 1990 Amendments, and also include minor clarifications to certain existing regulations.

**EFFECTIVE DATE:** These regulations take effect either 45 days after publication in the Federal Register or later if the Congress takes certain adjournments. If you want to know the effective date of the regulations call or write the Department of Education contact person.

**FOR FURTHER INFORMATION CONTACT:** Max Mueller, DPP, Office of Special Education Programs, Department of Education, 400 Maryland Ave. SW., Washington, DC 20202-2651. Telephone: (202) 732-1554. Deaf and hearing impaired individuals may call (202) 732-1100 for TDD services.

**SUPPLEMENTARY INFORMATION:** The 1990 Amendments change the name of the Office of Special Education personnel preparation program (Part D of the Act) from Training Personnel for the Education of Individuals with Disabilities to Training Personnel for the Education of Individuals with Disabilities. The name of the law itself is now Individuals with Disabilities Education Act (IDEA). These regulations, Grants for Personnel Training (34 CFR part 318), implement sections 631 (a) and (b) of the Act. Other aspects of Part D are regulated under 34 CFR parts 316, 319, and 320.

On June 14, 1991, the Secretary published a notice of proposed rulemaking (NPRM) for this program in the Federal Register at 56 FR 27474. The major issues related to these regulations are discussed in that announcement on page 27475, and are summarized here as follows:

The major purpose of the new regulations is to incorporate new program authorities mandated or authorized by the 1990 Amendments. In the pertinent part, the 1990 Amendments

require substantially increased attention to the interaction of special education and education of minority groups, and further place considerable emphasis on increasing the dissemination of information derived from supported projects. The 1990 Amendments also modified the career categories eligible for funding and amended the special projects authority to reflect important trends and priorities for serving children with disabilities.

Moreover, the Secretary is now authorized under IDEA to require (as appropriate or where relevant) attention to the content of training programs focused on training techniques, procedures, and practice designed to demonstrate the delivery of services in an array of regular, special education, and community settings; coordination or collaboration among personnel serving infants, toddlers, children, and youth with disabilities; and interdisciplinary preparation of trainees. The final regulations include these elements as requirements for all funded projects.

In addition, the final regulations include certain changes that are not required by the 1990 Amendments (changes that were proposed in the NPRM). These include changes in priorities based on review of 1991 annual priorities (as well as the new legislation), and a number of minor changes in organization and language that clarify the existing regulations and conform them more closely to the legislation.

As stated on page 27475 of the NPRM published on June 14, 1991, these final regulations do not contain definitions for the terms listed in the proposed rules because these terms have yet to be defined in accordance with the 1990 Amendments.

Finally, the NPRM invited comment on the current application selection criteria in subpart C of part 318, as modified in minor respects by the 1990 Amendments, in order to assist the Department in developing a future NPRM that will revise the selection criteria for all the discretionary grant programs (including part 318) authorized in Parts C through G of IDEA. The purpose of this activity will be to promote greater commonality in the criteria. The public comments received on the Part 318 selection criteria are discussed below and will be taken into account by the Department as a part of the later regulatory effort. Therefore the selection criteria that were included in the NPRM are included in the final regulations without changes.

These regulations constitute a step in implementing the America 2000 strategy for achieving the National Education

Goals agreed to by the President and the Governors. One aspect of the Secretary's plan for moving the Nation toward the National Education Goals is to foster better and more accountable schools and services. The Secretary seeks to increase the number and quality of qualified personnel in order to improve today's schools and services.

## Analysis of Comments and Changes

In response to the Secretary's invitation in the NPRM, ten parties submitted comments on the proposed regulations. An analysis of the comments and of the changes in the regulations since publication of the NPRM follows:

**Comment:** One commenter suggested that baccalaureate and masters level training was not sufficient for preparation of administrators and supervisors in special education and should be deleted from § 318.11(a).

**Discussion:** The Secretary agrees that baccalaureate and masters degree training is not appropriate in this area. Review of State certification requirements, and the changes in IDEA, support the commenter's position.

**Change:** The priority has been changed to delete consideration of baccalaureate and masters level training in administration and supervision.

**Comment:** One commenter expressed concern that reviewers of applications submitted under the Leadership Personnel priority in § 318.11(d) would give preference to doctoral level training over sub-doctoral advanced graduate training in selecting projects for support. The commenter recommended that, at least, sub-doctoral advanced training should be given priority within the leadership training program.

**Discussion:** The authorizing legislation stipulates that leadership training includes training in administration and supervision at the advanced graduate level as well as the doctoral level and does not provide a basis for giving priority emphasis to either level.

**Change:** None.

**Comment:** Four commenters suggested that the proposed selection criteria did not provide adequate incentives to attract increased participation by ethnic minorities and minority institutions, or by underrepresented populations. Two of these commenters specifically suggested addition of a 20 point criterion addressed in this area.

**Discussion:** As noted in the NPRM, the Office of Special Education is anticipating a separate effort in the near future geared specifically to changes in selection criteria for all the



discretionary grant programs. The Secretary therefore will deal with the issue in that context. However, it should be noted that the final regulations reflect increased emphasis on minority issues in two ways. First, to be considered for funding, all applicants must demonstrate how they will address the needs of minority children and how they will recruit and train minority personnel. See § 318.20(d). Second, individual priorities are established for (1) improving services for minorities; (2) training minority personnel; and (3) minority institutions. See § 318.11(l), (m) and (n).

*Change:* None.

*Comment:* One commenter suggested that public comment on priorities include consideration of projected funding levels.

*Discussion:* The primary purpose of the NPRM for this program was to solicit comments from the field on a range of priority areas proposed for funding under the authority of the Act. The Secretary may select annually one or more of these priority areas for funding. However, because program regulations are in effect over multiple years, and the budget information results from annual appropriations, it is not possible to provide funding estimates in regulations.

*Change:* None.

*Comment:* One commenter suggested the need for separate selection criteria for assigning bonus points to competitive priorities, and implied that more detailed criteria would be useful in connection with all priorities.

*Discussion:* The Secretary believes the current selection criteria reflect the most significant aspects of desired applications. However, as indicated in the NPRM, the Secretary intends to review the selection criteria in the near future, and this issue will be considered at that time. Moreover, EDGAR permits the Secretary to expand upon the priority descriptions contained in the final regulations by proposing more detailed competitive priorities and to assign additional points to these priorities. In addition, EDGAR permits the Secretary to propose more detailed absolute priorities, as well as to publish invitational priorities. (See 34 CFR 75.105).

*Change:* None.

*Comment:* One commenter noted that it is important to continue the "rural" priority.

*Discussion:* This priority is included in the new regulations in § 318.11(i).

*Change:* None.

*Comment:* One commenter recommended that training in assistive technology should be added to the priority in paragraph (j) of § 318.11 for training personnel to provide transition assistance from school to adult roles.

*Discussion:* The Secretary agrees with the commenter that assistive technology is especially important in the area of transition.

*Change:* The Priority has been modified to emphasize the importance of instructional and assistive technology in transition training programs.

*Comment:* One commenter recommended that separate competitions should be established for educational institutions based on size, number of students and geographic location, in addition to minority status.

*Discussion:* The Secretary is required by IDEA to provide for special consideration of minority institutions. There is no similar basis in law, nor in program history, to justify similar differentiation based on institutional size, number of students, or location.

*Change:* None.

*Comment:* One commenter recommended that these regulations recognize the existence of pools of potentially qualified minority staff in Head Start and day care programs to work with special needs children, and the differing preservice training needs of these staff members.

*Discussion:* The Secretary believes that several of the priorities listed in § 318.11, especially those dealing with needs of improving services for minorities and training minority personnel are worded broadly enough to address the specific concerns of this commenter.

*Change:* None.

#### Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

#### Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

#### Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed rules and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

#### List of Subjects in 34 CFR Part 318

Education, Education of individuals with disabilities, Education—training, Grant programs—education, Reporting and recordkeeping requirements, Student aid, Teachers.

Dated: September 11, 1991.

Lamar Alexander,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number 84.029—Training Personnel for the Education of Individuals with Disabilities)

The Secretary amends title 34 of the Code of Federal Regulations by revising part 318 to read as follows:

### PART 318—TRAINING PERSONNEL FOR THE EDUCATION OF INDIVIDUALS WITH DISABILITIES—GRANTS FOR PERSONNEL TRAINING

#### Subpart A—General

Sec.

318.1 What is the purpose of this program?

318.2 Who is eligible for an award?

318.3 What regulations apply to this program?

318.4 What definitions apply to this program?

#### Subpart B—What Kinds of Projects Does the Secretary Assist Under This Program?

318.10 What activities may the Secretary fund?

318.11 What priorities may the Secretary establish?

#### Subpart C—How Does the Secretary Make an Award?

318.20 What are the requirements for applicants?

318.21 How does the Secretary evaluate an application?

318.22 What selection criteria does the Secretary use to evaluate applications other than applications for special projects?

318.23 What selection criteria does the Secretary use to evaluate applications for special projects?

#### Subpart D—What Conditions Must a Grantee Meet?

318.30 What are the priorities for award of student fellowships and traineeships?

318.31 Is student financial assistance limited?

318.32 What are the student financial assistance criteria?

318.33 May the grantee use funds if a financially assisted student withdraws or is dismissed?

318.34 What are the reporting requirements under this program?



Authority: 20 U.S.C. 1431, 1434, and 1435, unless otherwise noted.

### Subpart A—General

#### § 318.1 What is the purpose of this program?

This program serves to increase the quantity and improve the quality of personnel available to serve infants, toddlers, children, and youth with disabilities through support of training programs for—

- (a) Special education, related services, early intervention;
- (b) Leadership, and
- (c) Special projects.

(Authority: 20 U.S.C. 1431)

#### § 318.2 Who is eligible for an award?

(a) The following are eligible for assistance under this part:

(1) Institutions of higher education and appropriate nonprofit agencies are eligible under § 318.1(a) and (b).

(2) Institutions of higher education, State agencies, and other appropriate nonprofit agencies are eligible under § 318.1(c).

(b) In order to receive a grant under § 318.1(a) or (b), an institution or agency must demonstrate that it meets State and professionally recognized standards for the training of personnel, as evidenced by appropriate State and professional accreditation, unless the grant is for the purpose of assisting the applicant agency or institution to meet those standards.

(Authority: 20 U.S.C. 1431)

#### § 318.3 What regulations apply to this program?

The following regulations apply to Training Personnel for the Education of Individuals with Disabilities—Grants for Personnel Training:

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations), part 75 (Direct Grant Programs), part 77 (Definitions that Apply to Department Regulations), part 79 (Intergovernmental Review of Department of Education Programs and Activities), part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments), part 81 (General Education Provisions Act—Enforcement), part 82 (New Restrictions on Lobbying), part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)), and part 86 (Drug-Free Schools and Campuses).

(b) The regulations in this part 318.

#### § 318.4 What definitions apply to this program?

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1:

Applicant  
Application  
Award  
Department  
EDGAR  
Fiscal year  
Grant period  
Local educational agency  
Nonprofit  
Preschool  
Private  
Project  
Public  
Secretary  
State  
State educational agency

(b) *Definitions specific to 34 CFR part 318.* The following terms used in this part are defined as follows:

*Act* means the Individuals with Disabilities Education Act (IDEA).

*Infants and toddlers with disabilities:*

(1) The term means children from birth through age two who need early intervention services because they—

(i) Are experiencing developmental delays, as measured by appropriate diagnostic instruments and procedures, in one or more of the following areas:

- (A) Cognitive development.
- (B) Physical development, including vision and hearing.
- (C) Language or speech development.
- (D) Psychosocial development.
- (E) Self-help skills; or

(ii) Have a diagnosed physical or mental condition that has a high probability of resulting in developmental delay.

(2) The term also includes children from birth through age two who are at risk of having substantial developmental delays if early intervention services are not provided.

(Authority: 20 U.S.C. 1400, 1431 (a) and (b), 1472)

### Subpart B—What Kinds of Projects Does the Secretary Assist Under This Program?

#### § 318.10 What activities may the Secretary fund?

(a) Projects supported under this program may provide training for degree, nondegree, certified, and noncertified personnel at associate degree through post-doctoral levels of preparation.

(b) The Secretary supports three types of projects under this program—

(1) Development of new programs to establish expanded capacity for quality preservice training;

(2) Improvement of existing programs designed to increase the capacity and quality of preservice training; and

(3) Special projects.

(c) The Secretary supports training programs in the following areas:

(1) Preservice training of personnel for careers in special education, related services, and early intervention, including careers in—

(i) Special education teaching, including speech-language pathology, audiology, adapted physical education, and instructional and assistive technology;

(ii) Related services for children with disabilities in educational and other settings; and

(iii) Early intervention and preschool services.

(2) Leadership training including—

(i) Supervision and administration at the advanced graduate, doctoral and post-doctoral levels;

(ii) Research at the doctoral and post-doctoral levels; and

(iii) Personnel preparation at the doctoral and post-doctoral levels.

(3) Special projects designed to include—

(i) Development, evaluation, and distribution of innovative approaches, curricula, and materials for personnel development; and

(ii) Other projects of national significance related to the preparation of personnel needed to serve infants, toddlers, children, and youth with disabilities.

(Authority: 20 U.S.C. 1431)

#### § 318.11 What priorities may the Secretary establish?

The Secretary may select annually one or more priority areas for funding including:

(a) *Preparation of personnel for careers in special education.* This priority supports preservice preparation of personnel for careers in special education. Preservice training includes additional training for currently employed teachers seeking additional degrees, certifications, or endorsements. Training at the baccalaureate, masters, or specialist level is appropriate. Under this priority "personnel" includes special education teachers, speech-language pathologists, audiologists, adapted physical education teachers, vocational educators, and instructive and assistive technology specialists.

(b) *Preparation of related services personnel.* This priority supports preservice preparation of individuals to



provide developmental, corrective, and other supportive services that assist children and youth with disabilities to benefit from special education. These include paraprofessional personnel, therapeutic recreation specialists, school social workers, health service providers, physical therapists (PT), occupational therapists (OT), school psychologists, counselors including rehabilitation counselors, interpreters, orientation and mobility specialists, respite care providers, art therapists, volunteers, physicians, and other related services personnel. Projects to train personnel identified as special education personnel in the regulations in this part are not appropriate, even if those personnel may be considered related services personnel in other settings.

This program is not designed for general training. Projects must include inducements and preparation to increase the probability that graduates will direct their efforts toward supportive services to special education. For example, a project in occupational therapy might support a special component on pediatric or juvenile psychiatric OT, support those students whose career goal is OT in the schools, or provide for practica and internships in school settings.

(c) *Training early intervention and preschool personnel.* This priority supports projects that are designed to provide preservice preparation of personnel who serve infants, toddlers, and preschool children with disabilities, and their families. Personnel may be prepared to provide short-term services or long-term services that extend into a child's school program. The proposed training program must have a clear and limited focus on the special needs of children within the age range from birth to five, and must include consideration of family involvement in early intervention and preschool services. Training programs under this priority must have a significant interdisciplinary focus.

(d) *Preparation of leadership personnel.* This priority supports projects that are designed to provide preservice advanced graduate, doctoral, and post-doctoral preparation in administration and supervision; or doctoral and post-doctoral level training in research or personnel preparation.

(e) *Special projects.* (1) This priority supports projects that include development, evaluation, and distribution of innovative approaches to personnel preparation; development of curriculum materials to prepare personnel to educate or provide early intervention services; and other projects of national significance related to the

preparation of personnel needed to serve infants, toddlers, children, and youth with disabilities.

(2) Appropriate areas of interest include—

(i) Preservice training programs to prepare regular educators to work with children and youth with disabilities and their families;

(ii) Training teachers to work in community and school settings with children and youth with disabilities and their families;

(iii) Inservice and preservice training of teachers to work with infants, toddlers, children, and youth with disabilities and their families;

(iv) Inservice and preservice training of personnel to work with minority infants, toddlers, children, youth with disabilities and their families;

(v) Preservice and inservice training of special education and related services personnel in instructive and assistive technology to benefit infants, toddlers, children, and youth with disabilities; and

(vi) Recruitment and retention of special education, related services, and early intervention personnel.

(3) Both inservice and preservice training must include a component that addresses the coordination among all service providers, including regular educators.

(f) *Utilizing innovative recruitment and retention strategies.* This priority supports projects to develop emerging and creative sources of supply of personnel with degrees and certification in appropriate disciplines, and innovative strategies related to recruitment and retention of personnel.

(g) *Promoting full qualifications for personnel serving infants, toddlers, children, and youth with disabilities.* This priority supports projects designed specifically to train personnel who are working with less than full certification or outside their field of specialization, to assist them in becoming fully qualified. Student incentives; extension, summer, and evening programs; internships; alternative certification plans; and other innovative practices are appropriate under this priority.

(h) *Training personnel to serve low incidence disabilities.* This priority supports projects to train teachers of children with serious emotional disturbance; visual impairments, including blindness; hearing impairments, including deafness; orthopedic impairments; other health impairments; and severe and multiple disabilities.

(i) *Training personnel to work in rural areas.* This priority projects to train personnel to serve infants, toddlers,

children, and youth with disabilities in rural areas. Projects, including curricula, procedures, practica, and innovative use of technology, must be designed to provide training to assist personnel to work with parents, teachers, and administrators in these special environments. Special strategies must be designed to recruit personnel from rural areas who will most likely return to those areas.

(j) *Training personnel to provide transition assistance from school to adult roles.* This priority supports projects for preparation of personnel who assist youth with disabilities in their transition from school to adult roles. Personnel may be prepared to provide short-term transition services, long-term structured employment services, or instruction in community and school settings with secondary school students. It is especially important that preparation of transition personnel include training in instructional and assistive technology.

(k) *Preparation of paraprofessionals.* This priority supports projects for the preparation of paraprofessionals. This includes programs to train teacher aids, job coaches, interpreters, therapy assistants, and other personnel who provide support to professional staff in delivery of services to infants, toddlers, children, and youth with disabilities.

(l) *Improving services for minorities.* This priority supports projects to prepare personnel to serve infants, toddlers, children, and youth with disabilities who, because of minority status, require that personnel obtain professional competencies in addition to those needed to teach other children with similar disabilities. Projects funded under this priority must focus on specific minority populations, determine the additional competencies that are needed by professionals serving those populations, and develop those competencies.

(m) *Training minority personnel.* This priority supports projects to recruit and prepare minority individuals and individuals with disabilities for careers in special education, related services, and early intervention, including leadership personnel.

(n) *Minority institutions.* This priority supports grants to Historically Black Colleges and Universities and other institutions of higher education whose minority student enrollment is at least 25 percent. Grants may provide training in any of the areas covered in other priorities, and must be designed to increase the capabilities of the institution in appropriate training areas.



(Authority: 20 U.S.C. 1431)

### Subpart C—How Does the Secretary Make an Award?

#### § 318.20 What are the requirements for applicants?

(a) An applicant shall demonstrate that the proposed project is consistent with the needs for personnel, including personnel to provide special education services to children with limited English proficiency, identified by the comprehensive system of personnel development of the State or States typically employing program graduates.

(b) An applicant under this program shall address—

(1) Training techniques and procedures designed to foster collaboration among special teachers, regular teachers, administrators, related service personnel, early intervention personnel, and parents;

(2) Training techniques, procedures, and practica designed to demonstrate the delivery of services in an array of regular, special education, and community settings; and

(3) Interdisciplinary preparation of trainees.

(c) An applicant shall demonstrate how it will address, in whole or in part, the needs of infants, toddlers, children, and youth with disabilities from minority backgrounds.

(d) An applicant shall present a detailed description of strategies for recruitment and training of members of minority groups and persons with disabilities.

(Approved by the Office of Management and Budget under control number 1820-0028.)

(Authority: 20 U.S.C. 1410 and 1431)

#### § 318.21 How does the Secretary evaluate an application?

(a) The Secretary evaluates an application on the basis of the criteria in §§ 318.22 and 318.23.

(b) The Secretary awards up to 100 points for these criteria.

(c) The maximum possible score for each criterion is indicated in parentheses.

(Authority: 20 U.S.C. 1431)

#### § 318.22 What selection criteria does the Secretary use to evaluate applications other than applications for special projects?

The Secretary uses the following criteria to evaluate all applications other than applications for special projects.

(a) *Impact on critical present and projected need.* (30 points) The Secretary reviews each application to determine the extent to which the training will have a significant impact

on critical present and projected State, regional, or national needs in the quality or the quantity of personnel serving infants, toddlers, children, and youth with disabilities. The Secretary considers—

(1) The significance of the personnel needs to be addressed to the provision of special education, related services, and early intervention. Significance of need identified by the applicant may be shown by—

(i) Evidence of critical shortages of personnel to serve infants, toddlers, children, and youth with disabilities, including those with limited English proficiency, in targeted specialty or geographic areas, as demonstrated by data from the State Comprehensive System of Personnel Development; reports from the Clearinghouse on Careers and Employment of Personnel serving children and youth with disabilities; or other indicators of need that the applicant demonstrates are relevant, reliable, and accurate; or

(ii) Evidence showing significant need for improvement in the quality of personnel providing special education, related services and early intervention services, as shown by comparisons of actual and needed skills of personnel in targeted specialty or geographic areas; and

(2) The impact the proposed project will have on the targeted need. Evidence that the project results will have an impact on the targeted needs may include—

(i) The projected number of graduates from the project each year who will have necessary competencies and certification to affect the need;

(ii) For ongoing programs, the extent to which the applicant's projections are supported by the number of previous program graduates that have entered the field for which they received training, and the professional contributions of those graduates; and

(iii) For new programs, the extent to which program features address the projected needs, the applicant's plan for helping graduates locate appropriate employment in the area of need, and the program features that ensure that graduates will have competencies needed to address identified qualitative needs.

(b) *Capacity of the institution.* (25 points) The Secretary reviews each application to determine the capacity of the institution or agency to train qualified personnel, including consideration of—

(1) The qualifications and accomplishments of the project director and other key personnel directly involved in the proposed training

program, including prior training, publications, and other professional contributions;

(2) The amount of time each key person plans to commit to the project;

(3) How the applicant, as a part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or disability;

(4) The adequacy of resources, facilities, supplies, and equipment that the applicant plans to commit to the project;

(5) The quality of the practicum training settings, including evidence that they are sufficiently available; apply state-of-the-art services and model teaching practices, materials, and technology; provide adequate supervision to trainees; offer opportunities for trainees to teach; and foster interaction between students with disabilities and their nondisabled peers;

(6) The capacity of the applicant to recruit well-qualified students;

(7) The experience and capacity of the applicant to assist local public schools and early intervention service agencies in providing training to these personnel, including the development of model practicum sites; and

(8) The extent to which the applicant cooperates with the State educational agency, the State designated lead agency under Part H of the Act, other institutions of higher education, and other appropriate public and private agencies in the region served by the applicant in identifying personnel needs and plans to address those needs.

(c) *Plan of operation.* (25 points) The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) High quality in the design of the project;

(2) The extent to which the plan of management ensures effective, proper, and efficient administration of the project;

(3) How well the objectives of the project relate to the purpose of the program;

(4) The way the applicant plans to use its resources and personnel to achieve each objective;

(5) The extent to which the application includes a delineation of competencies that program graduates will acquire and how the competencies will be evaluated;

(6) The extent to which substantive content and organization of the program—

(i) Are appropriate for the students' attainment of professional knowledge



and competencies deemed necessary for the provision of quality educational and early intervention services for infants, toddlers, children, and youth with disabilities; and

(ii) Demonstrate an awareness of methods, procedures, techniques, technology, and instructional media or materials that are relevant to the preparation of personnel who serve infants, toddlers, children, and youth with disabilities; and

(7) The extent to which program philosophy, objectives, and activities implement current research and demonstration results in meeting the educational or early intervention needs of infants, toddlers, children, and youth with disabilities.

(d) *Evaluation plan.* (10 points) The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation—

(1) Are appropriate for the project;

(2) To the extent possible, are objective and produce data that are quantifiable, including, but not limited to, the number of trainees graduated and hired; and

(3) Provide evidence that evaluation data and student follow-up data are systematically collected and used to modify and improve the program. (See 34 CFR 75.590, Evaluation by the grantee.)

(e) *Budget and cost-effectiveness.* (10 points) The Secretary reviews each application to determine the extent to which—

(1) The budget for the project is adequate to support the project activities;

(2) Costs are reasonable in relation to the objectives of the project; and

(3) The applicant presents appropriate plans for the institutionalization of Federally supported activities into basic program operations.

#### **§ 318.23 What selection criteria does the Secretary use to evaluate applications for special projects?**

The Secretary uses the following criteria to evaluate special projects applications:

(a) *Anticipated project results.* (20 points) The Secretary reviews each application to determine the extent to which the project will meet present and projected needs under Parts B and H of the Act in special education, related services, or early intervention services personnel development.

(b) *Program content.* (20 points) The Secretary reviews each application to determine—

(1) The project's potential for national significance, its potential for replication and effectiveness, and the quality of its plan for dissemination of the results of the project;

(2) The extent to which substantive content and organization of the program—

(i) Are appropriate for the attainment of knowledge that is necessary for the provision of quality educational and early intervention services to infants, toddlers, children, and youth with disabilities; and

(ii) Demonstrate an awareness of relevant methods, procedures, techniques, technology, and instructional media or materials that can be used in the development of a model to prepare personnel to serve infants, toddlers, children, and youth with disabilities; and

(3) The extent to which program philosophy, objectives, and activities are related to the educational or early intervention needs of infants, toddlers, children, and youth with disabilities.

(c) *Plan of operation.* (15 points) The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) High quality in the design of the project;

(2) An effective plan of management that ensures proper and efficient administration of the project;

(3) How the objectives of the project relate to the purpose of the program; and

(4) The way the applicant plans to use its resources and personnel to achieve each objective.

(d) *Evaluation plan.* (15 points) The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation—

(1) Are appropriate for the project; and

(2) To the extent possible, are objective and produce data that are quantifiable. (See 34 CFR 75.590, Evaluation by the grantee.)

(e) *Quality of key personnel.* (15 points) The Secretary reviews each application to determine the quality of the key personnel the applicant plans to use in the project, including—

(1) The qualifications of the project director;

(2) The qualifications of each of the other key personnel to be used in the project;

(3) The time that each of the key personnel plans to commit to the project;

(4) How the applicant, as a part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without

regard to race, color, national origin, gender, age, or disability; and

(5) Evidence of the applicant's past experience and training in fields related to the objectives of the project.

(f) *Adequacy of resources.* (5 points)

The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the project, including facilities, equipment, and supplies.

(g) *Budget and cost effectiveness.* (10 points) The Secretary reviews each application to determine the extent to which—

(1) The budget is adequate to support to project; and

(2) Costs are reasonable in relation to the objectives of the project.

(Authority: 20 U.S.C. 1431)

#### **Subpart D—What Conditions Must a Grantee Meet?**

##### **§ 318.30 What are the priorities for award of student fellowships and traineeships?**

A grantee shall give priority consideration in the selection of qualified recipients of fellowships and traineeships to individuals from disadvantaged backgrounds, including minorities and individuals with disabilities who are underrepresented in the teaching profession or in the specializations in which they are being trained.

(Authority: 20 U.S.C. 1431)

##### **§ 318.31 Is student financial assistance limited?**

The sum of the assistance provided to a student under this part and any other assistance provided the student may not exceed the student's cost of attendance. Cost of attendance is defined as—

(a) Tuition and fees normally assessed a student carrying the same academic workload, as determined by the institution, and including costs for rental or purchase of any equipment, materials, or supplies required of all students to the same course of study;

(b) An allowance for books, supplies, transportation, and miscellaneous personal expenses for a student attending the institution on at least a half-time basis, as determined by the institution;

(c) An allowance, as determined by the institution, for room and board costs incurred by the student that—

(1) Will be not less than \$1,500 for students without dependents residing at home with parents;

(2) Will be the standard amount that the institution normally assesses its residents for room and board for students without dependents residing in



institutionally owned or operated housing; and

(3) Will be based for all other students on the expenses reasonably incurred for room and board outside the institution, except that the amount may not be less than \$2,500;

(d) For less than half-time students (as determined by the institution), tuition and fees and an allowance for books, supplies, and transportation (as determined by the institution) and dependent care expenses (in accordance with paragraph (g) of this section);

(e) For a student engaged in a program of study by correspondence, only tuition and fees; and, if required, books and supplies, travel, and room and board costs incurred specially in fulfilling a required period of residential training;

(f) For a student enrolled in an academic program that normally includes a formal program of study abroad, reasonable costs associated with the study as determined by the institution;

(g) For a student with one or more dependents, an allowance, as determined by the institution, based on the expenses reasonably incurred for dependent care based on the number and age of the dependents;

(h) For a student with a disability, an allowance, as determined by the institution, for those expenses related to

his or her disability, including special services, transportation, equipment, and supplies that are reasonably incurred and not provided for by other assisting agencies; and

(i) For a student receiving all or part of his or her instruction by means of telecommunications technology, no distinction may be made with respect to the mode of instruction in determining costs, but this paragraph may not be construed to permit including the cost of rental or purchase of equipment.

(Authority: 20 U.S.C. 1087)

**§ 318.32 What are the student financial assistance criteria?**

Direct financial assistance may only be paid to a student in a preservice program, and only if—

(a) The student is qualified for admission to the program of study;

(b) The student maintains satisfactory progress in a course of study as defined in 34 CFR 608.7; and

(c) The student is a citizen or national of the United States.

(Authority: 20 U.S.C. 1087)

**§ 318.33 May the grantee use funds if a financially assisted student withdraws or is dismissed?**

Financial assistance awarded to a student that is unexpended because the student withdraws or is dismissed from

the training program may be used for financial assistance to other students during the grant period.

(Authority: 20 U.S.C. 1087)

**§ 318.34 What are the reporting requirements under this program?**

The Secretary may require recipients to prepare reports describing their procedures, findings, and other relevant information in a form that will maximize the dissemination and use of all procedures, findings, and information. The recipient shall deliver products, as appropriate, to the Regional and Federal Resource Centers, the Clearinghouses, and the technical assistance to parents program assisted under Parts C and D of the Act; as well as to the National Diffusion Network, the ERIC Clearinghouse on the Handicapped and Gifted, the Child and Adolescent Service Systems Program under the National Institute of Mental Health, appropriate parent and professional organizations, organizations representing individuals with disabilities, and any other entities that the Secretary determines to be appropriate.

(Authority: 20 U.S.C. 1410)

[FR Doc. 91-26942 Filed 11-6-91; 8:45 am]

BILLING CODE 4000-01-M



**DEPARTMENT OF EDUCATION****Office of Special Education Programs**

[CFDA No. 84.029]

**Notice Inviting Applications for New Awards Under Training Personnel for the Education of Individuals With Disabilities for Fiscal Year 1992****Note To Applicants**

This notice is a complete application package. The notice contains information,

application forms and instructions needed to apply for a grant under this competition.

**Purpose of Program**

This program serves to increase the quantity and improve the quality of personnel available to serve infants, toddlers, children, and youth with disabilities through support of training programs for—

- (a) Special education, related services, early intervention;
- (b) Leadership, and

(c) Special projects.

The estimates of funding levels and awards in this notice do not bind the Department of Education to a specific level of funding or number of grants, unless the amount is otherwise specified by statute or regulation.

**TRAINING PERSONNEL FOR THE EDUCATION OF THE HANDICAPPED**

[Application notice for fiscal year 1992]

Title and CFDA No.	Deadline for transmittal of applications	Deadline for intergovernmental review	Available funds	Estimated range of awards (per year)	Estimated size of awards (per year)	Estimated No. of awards	Project period in months
Preparation of Leadership Personnel (84.029D)	01/10/92	03/10/92	2,500,000	75,000-125,000	100,000	25	Up to 60.
Special Projects (84.029K)	01/10/92	03/10/92	3,500,000	75,000-125,000	100,000	35	Up to 60.
Preparation of personnel for careers in special education (84.029B)	01/10/92	03/10/92	7,000,000	75,000-125,000	100,000	70	Up to 48.
Preparation of related services personnel (84.029F)	01/10/92	03/10/92	4,500,000	75,000-125,000	100,000	45	Up to 48.
Training early intervention and preschool personnel (84.029Q)	01/10/92	03/10/92	5,500,000	75,000-125,000	100,000	55	Up to 60.
Minority Institutions (84.029e)	01/10/92	03/10/92	2,000,000	75,000-125,000	100,000	20	Up to 48.
Training personnel to serve low-incidence disabilities. (84.029A)	01/10/92	03/10/92	2,000,000	75,000-125,000	100,000	20	Up to 48.

**Applicable Regulations**

(a) The Education Department General Administrative Regulations (EDGAR) 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, and 86; and (b) final program regulations for Training Personnel for the Education of Individuals with Disabilities—Grants for Personnel Training, 34 CFR Part 318, published in this issue of the **Federal Register**.

**Priorities**

Under 34 CFR 75.105(c)(3) and 34 CFR part 318 the Secretary gives an absolute preference to applications which meet the following priorities. The Secretary funds under this program only those applications that meet one or more of these absolute priorities. Under competitive priorities the Secretary may select an application that meets a priority over an application of comparable merit that does not meet the priority. Absolute priorities numbers 3-7 have competitive priorities within them.

**Absolute Priority 1—Preparation of Leadership Personnel, CFDA No. 84.029D**

This priority supports projects that are designed to provide preservice advanced graduate, doctoral, and post-doctoral preparation in administration and supervision; or doctoral and post-

doctoral level training in research or personnel preparation.

Under 34 CFR 75.105(c)(1) the Secretary is particularly interested in applications that meet the following invitational priority. However, an application that meets this invitational priority does not receive a competitive or absolute preference over other applications that do not meet this invitational priority.

**Training Minority Leadership Personnel**

The Individuals with Disabilities Education Act (IDEA) in section 610(j)(2) (A) and (B) recommends implementing policies for preparing minorities in special education and related services. The Department believes that one aspect of this policy is to support post-doctoral level training for minority individuals. For this reason, the Secretary particularly invites applications that include activities to recruit minority individuals and individuals from underrepresented populations for post-doctoral level training to increase their participation in leadership positions in the field of special education and related services.

**Eligible Applicants:** Eligible applicants are institutions of higher education and appropriate non-profit agencies.

**Absolute Priority 2—Special Projects, CFDA No. 84.029K**

This priority supports projects that include development, evaluation, and distribution of innovative approaches to personnel preparation; development of curriculum materials to prepare personnel to educate or provide early intervention services; and other projects of national significance related to the preparation of personnel needed to serve infants, toddlers, children, and youth with disabilities.

Appropriate areas of interest include—

- (1) Preservice training programs to prepare regular educators to work with children and youth with disabilities and their families;
- (2) Training teachers to work in community and school settings with children and youth with disabilities and their families;
- (3) Inservice and preservice training of teachers to work with infants, toddlers, children, and youth with disabilities and their families;
- (4) Inservice and preservice training of personnel to work with minority infants, toddlers, children, and youth with disabilities and their families;
- (5) Preservice and inservice training of special education and related services personnel in instructive and assistive



technology to benefit infants, toddlers, children, and youth with disabilities; and

(6) Recruitment and retention of special education, related services, and early intervention personnel.

Both inservice and preservice training must include a component that addresses the coordination among all service providers, including regular educators.

Under 34 CFR 75.105(c)(1) the Secretary is particularly interested in applications that meet the following invitational priority. However, an application that meets this invitational priority does not receive a competitive or absolute preference over other applications that do not meet this invitational priority.

#### *Attention Deficit Disorders*

The Secretary particularly invites applications for projects that develop new inservice and preservice training for special education and regular classroom teachers in order to address the needs of children with attention deficit disorders (ADD). In the fiscal year 1992 House Appropriation Committee report, the committee indicated that \$1,500,000 of fiscal year 1992 funds be used for this purpose, noting that educators and administrators know very little about effectively meeting the educational needs of children with attention deficit disorder. Consequently, there is a tremendous need for inservice and preservice training for educators at all levels.

**Eligible Applicants:** Eligible applicants are institutions of higher education, State educational agencies, and other appropriate non-profit organizations.

#### *Absolute Priority 3—Preparation of Personnel for Careers in Special Education, CFDA No. 84.029B*

This priority supports preservice preparation of personnel for careers in special education. Preservice training includes additional training for currently employed teachers seeking additional degrees, certifications, or endorsements. Training at the baccalaureate, masters, or specialist level is appropriate. Under this priority "personnel" includes special education teachers, speech-language pathologists, audiologists, adapted physical education teachers, vocational educators, and instructive and assistive technology specialists. Training of administrators and supervisors at the masters level is also appropriate under this priority.

Within this competition, the Secretary gives preference to the applications that

meet one or more of the following competitive priorities. An application that meets one or more of these competitive priorities is selected over applications of comparable merit that do not meet these priorities. These competitive priorities are described more fully in a later section of this announcement.

Utilizing innovative recruitment and retention strategies.

Promoting full qualifications for personnel serving infants, toddlers, children, and youth with disabilities.

Training personnel to work in rural areas.

Training personnel to provide transition assistance from school to adult roles.

Improving services for minorities.

Training minority personnel.

**Eligible Applicants:** Eligible applicants are institutions of higher education and appropriate non-profit organizations.

#### *Absolute Priority 4—Preparation of Related Services Personnel, CFDA No. 84.029F*

This priority supports preservice preparation of individuals to provide developmental, corrective, and other supportive services that assist children and youth with disabilities to benefit from special education. These include paraprofessional personnel, therapeutic recreation specialists, school social workers, health service providers, physical therapists (PT), occupational therapists (OT), school psychologists, counselors including rehabilitation counselors, interpreters, orientation and mobility specialists, respite care providers, art therapists, volunteers, physicians, and other related services personnel. Projects to train personnel identified as special education personnel in the regulations in this part are not appropriate, even if those personnel may be considered related services personnel in other settings.

This program is not designed for general training. Projects must include inducements and preparation to increase the probability that graduates will direct their efforts toward supportive services to special education. For example, a project in occupational therapy might support a special component on pediatric or juvenile psychiatric OT, support those students whose career goal is OT in the schools, or provide for practice and internships in school settings.

Within this competition, the Secretary gives preference to the applications that meet one or more of the following competitive priorities. An application that meets one or more of these

competitive priorities is selected over applications of comparable merit that do not meet these priorities. These competitive priorities are described more fully in a later section of this announcement.

Utilizing innovative recruitment and retention strategies.

Promoting full qualifications for personnel serving infants, toddlers, children, and youth with disabilities.

Training personnel to work in rural areas.

Preparation of paraprofessionals.

Improving services for minorities.

Training minority personnel.

Under 34 CFR 75.105(c)(1) the Secretary is particularly interested in applications that meet the following invitational priority. However, an application that meets this invitational priority does not receive competitive or absolute preference over other applications that do not meet this invitational priority.

#### *Training Interpreters for Children with Hearing Impairments, Including the Deaf*

The Secretary particularly invites applications for projects that train educational interpreters for children with hearing impairments, including deafness. In the fiscal year 1992 House Appropriation Committee report, the committee indicated that \$1,000,000 of fiscal year 1992 funds be used for this purpose, noting that there is a tremendous need for training for educational interpreters at all levels.

**Eligible Applicants:** Eligible applicants are institutions of higher education and appropriate non-profit organizations.

#### *Absolute Priority 5—Training Early Intervention and Preschool Personnel, CFDA 84.029Q*

This priority supports projects that are designed to provide preservice preparation of personnel who serve infants, toddlers, and preschool children with disabilities, and their families. Personnel may be prepared to provide short-term services or long-term services that extend into a child's school program. The proposed training program must have a clear and limited focus on the special needs of children within the age range from birth to five, and must include consideration of family involvement in early intervention and preschool services. Training programs under this priority must have a significant interdisciplinary focus.

Within this competition, the Secretary gives preference to the applications that meet one or more of the following



competitive priorities. An application that meets one or more of these competitive priorities is selected over applications of comparable merit that do not meet these priorities. These competitive priorities are described more fully in a later section of this announcement.

Utilizing innovative recruitment and retention strategies.  
Promoting full qualifications for personnel serving infants, toddlers, children, and youth with disabilities.  
Training personnel to work in rural areas.  
Preparation of paraprofessionals.  
Improving services for minorities.  
Training minority personnel.

**Eligible Applicants:** Eligible applicants are institutions of higher education and appropriate non-profit organizations.

**Absolute Priority 6—Minority Institutions, 84.029E**

This priority supports grants to Historically Black Colleges and Universities and other institutions of higher education whose minority student enrollment is at least 25 percent. Grants may provide training in any of the areas covered in other priorities, and must be designed to increase the capabilities of the institution in appropriate training areas.

Within this competition, the Secretary gives preference to the applications that meet one or more of the following competitive priorities. An application that meets one or more of these competitive priorities is selected over applications of comparable merit that do not meet these priorities. These competitive priorities are described more fully in a later section of this announcement.

Improving services for minorities.  
Training minority personnel.

**Eligible Applicants:** Eligible applicants are Historically Black Colleges and Universities and other institutions of higher education whose minority student enrollment is at least 25 percent.

**Absolute Priority 7—Training Personnel to Serve Low Incidence Disabilities, CFDA No. 84.029A**

This priority supports projects to train teachers of children with serious emotional disturbance; visual impairments, including blindness; hearing impairments, including deafness; orthopedic impairments; other health impairments; and severe and multiple disabilities.

Within this competition, the Secretary gives preference to the applications that

meet one or more of the following competitive priorities. An application that meets one or more of these competitive priorities is selected over applications of comparable merit that do not meet these priorities. These competitive priorities are described more fully in a later section of this announcement.

Utilizing innovative recruitment and retention strategies.  
Promoting full qualifications for personnel serving infants, toddlers, children, and youth with disabilities.  
Training personnel to work in rural areas.  
Training personnel to provide transition assistance from school to adult roles.  
Improving services for minorities.  
Training minority personnel.

**Competitive Priorities**

As noted in connection with each absolute priority, the Secretary gives preference to applications that meet one or more of the following competitive priorities. Under each absolute priority the Secretary may select an application that meets a competitive priority over an application of comparable merit that does not meet the competitive priority.

**• Competitive Preference Priority 1—Utilizing Innovative Recruitment and Retention Strategies**

This priority supports projects to develop emerging and creative sources of supply of personnel with degrees and certification in appropriate disciplines, and innovative strategies related to recruitment and retention of personnel.

**• Competitive Preference Priority 2—Promoting Full Qualifications for Personnel Serving Infants, Toddlers, Children, and Youth With Disabilities**

This priority supports projects designed specifically to train personnel who are working with less than full certification or outside their field of specialization, to assist them in becoming fully qualified. Student incentives; extension, summer and evening programs; internships; alternative certification plans; and other innovative practices are appropriate under this priority.

**• Competitive Preference Priority 3—Training Personnel to Work in Rural Areas**

This priority supports projects to train personnel to serve infants, toddlers, children, and youth with disabilities in rural areas. Projects, including curricula, procedures, practica, and innovative use of technology, must be designed to provide training to assist personnel to work with parents, teachers, and

administrators in these special environments. Special strategies must be designed to recruit personnel from rural areas who will most likely return to those areas.

**• Competitive Preference Priority 4—Training Personnel To Provide Transition Assistance From School to Adult Roles**

This priority supports projects for preparation of personnel who assist youth with disabilities in their transition from school to adult roles. Personnel may be prepared to provide short-term transitional services, long-term structured employment services, or instruction in community and school settings with secondary school students. It is especially important that preparation of transition personnel include training in instructional and assistive technology.

**• Competitive Preference Priority 5—Preparation of Paraprofessionals**

This priority supports projects for the preparation of paraprofessionals. This includes programs to train teacher aids, job coaches, interpreters, therapy assistants, and other personnel who provide support to professional staff in delivery of services to infants, toddlers, children, and youth with disabilities.

**• Competitive Preference Priority 6—Improving Services for Minorities**

This priority supports projects to prepare personnel to serve infants, toddlers, children, and youth with disabilities who, because of minority status, require that personnel obtain professional competencies in addition to those needed to teach other children with similar disabilities. Projects funded under this priority must focus on specific minority populations, determine the additional competencies that are needed by professionals serving those populations, and develop those competencies.

**Competitive Preference Priority 7—Training Minority Personnel**

This priority supports projects to recruit and prepare minority individuals and individuals with disabilities for careers in special education, related services, and early intervention, including leadership personnel.

**Selection Criteria**

The Secretary uses the following criteria to evaluate special projects applications:

(a) *Anticipated project results.* (20 points) The Secretary reviews each application to determine the extent to



which the project will meet present and projected needs under Parts B and H of the Act in special education, related services, or early intervention services personnel development.

(b) *Program content.* (20 points) The Secretary reviews each application to determine—

(1) The project's potential for national significance, its potential for replication and effectiveness, and the quality of its plan for dissemination of the results of the project;

(2) The extent to which substantive content and organization of the program—

(i) Are appropriate for the attainment of knowledge that is necessary for the provision of quality educational and early intervention services to infants, toddlers, children, and youth with disabilities; and

(ii) Demonstrate an awareness of relevant methods, procedures, techniques, technology, and instructional media or materials that can be used in the development of a model to prepare personnel to serve infants, toddlers, children, and youth with disabilities; and

(3) The extent to which program philosophy, objectives, and activities are related to the educational or early intervention needs of infants, toddlers, children, and youth with disabilities.

(c) *Plan of operation.* (15 points) The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) High quality in the design of the project;

(2) An effective plan of management that ensures proper and efficient administration of the project;

(3) How the objectives of the project relate to the purpose of the program; and

(4) The way the applicant plans to use its resources and personnel to achieve each objective.

(d) *Evaluation plan.* (15 points) The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation—

(1) Are appropriate for the project; and

(2) To the extent possible, are objective and produce data that are quantifiable. (See 34 CFR 75.590, Evaluation by the grantee.)

(e) *Quality of key personnel.* (15 points) The Secretary reviews each application to determine the quality of the key personnel the applicant plans to use in the project, including—

(1) The qualifications of the project director;

(2) The qualifications of each of the other key personnel to be used in the project;

(3) The time that each of the key personnel plans to commit to the project;

(4) How the applicant, as a part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or disability; and

(5) Evidence of the applicant's past experience and training in fields related to the objectives of the project.

(f) *Adequacy of resources.* (5 points) The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the project, including facilities, equipment, and supplies.

(g) *Budget and cost effectiveness.* (10 points) The Secretary reviews each application to determine the extent to which—

(1) The budget is adequate to support the project; and

(2) Costs are reasonable in relation to the objectives of the project.

The Secretary uses the following criteria to evaluate all applications other than applications for special projects.

(a) *Impact on critical present and projected need.* (30 points) The Secretary reviews each application to determine the extent to which the training will have a significant impact on critical present and projected State, regional, or national needs in the quality or the quantity of personnel serving infants, toddlers, children, and youth with disabilities. The Secretary considers—

(1) The significance of the personnel needs to be addressed to the provision of special education, related services, and early intervention. Significance of need identified by the applicant may be shown by—

(i) Evidence of critical shortages of personnel to serve infants, toddlers, children, and youth with disabilities, including those with limited English proficiency, in targeted specialty or geographic areas, as demonstrated by data from the State Comprehensive System of Personnel Development; reports from the Clearinghouse on Careers and Employment of Personnel serving children and youth with disabilities; or other indicators of need that the applicant demonstrates are relevant, reliable, and accurate; or

(ii) Evidence showing significant need for improvement in the quality of personnel providing special education, related services and early intervention services, as shown by comparisons of actual and needed skills of personnel in

targeted specialty or geographic areas; and

(2) The impact the proposed project will have on the targeted need. Evidence that the project results will have an impact on the targeted needs may include—

(i) The projected number of graduates from the project each year who will have necessary competencies and certification to affect the need;

(ii) For ongoing programs, the extent to which the applicant's projections are supported by the number of previous program graduates that have entered the field for which they received training, and the professional contributions of those graduates; and

(iii) For new programs, the extent to which program features address the projected needs, the applicant's plan for helping graduates locate appropriate employment in the area of need, and the program features that ensure that graduates will have competencies needed to address identified qualitative needs.

(b) *Capacity of the institution.* (25 points) The Secretary reviews each application to determine the capacity of the institution or agency to train qualified personnel, including consideration of—

(1) The qualifications and accomplishments of the project director and other key personnel directly involved in the proposed training program, including prior training, publications, and other professional contributions;

(2) The amount of time each key person plans to commit to the project;

(3) How the applicant, as a part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or disability;

(4) The adequacy of resources, facilities, supplies, and equipment that the applicant plans to commit to the project;

(5) The quality of the practicum training settings, including evidence that they are sufficiently available; apply state-of-the-art services and model teaching practices, materials, and technology; provide adequate supervision to trainees; offer opportunities for trainees to teach; and foster interaction between students with disabilities and their nondisabled peers;

(6) The capacity of the applicant to recruit well-qualified students;

(7) The experience and capacity of the applicant to assist local public schools and early intervention service agencies in providing training to these personnel,



including the development of model practicum sites; and

(8) The extent to which the applicant cooperates with the State educational agency, the State designated lead agency under Part H of the Act, other institutions of higher education, and other appropriate public and private agencies in the region served by the applicant in identifying personnel needs and plans to address those needs.

(c) *Plan of operation.* (25 points) The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) High quality in the design of the project;

(2) The extent to which the plan of management ensures effective, proper, and efficient administration of the project;

(3) How well the objectives of the project relate to the purpose of the program;

(4) The way the applicant plans to use its resources and personnel to achieve each objective;

(5) The extent to which the application includes a delineation of competencies that program graduates will acquire and how the competencies will be evaluated;

(6) The extent to which substantive content and organization of the program—

(i) Are appropriate for the students' attainment of professional knowledge and competencies deemed necessary for the provision of quality educational and early intervention services for infants, toddlers, children, and youth with disabilities; and

(ii) Demonstrate an awareness of methods, procedures, techniques, technology, and instructional media or materials that are relevant to the preparation of personnel who serve infants, toddlers, children, and youth with disabilities; and

(7) The extent to which program philosophy, objectives, and activities implement current research and demonstration results in meeting the educational or early intervention needs of infants, toddlers, children, and youth with disabilities.

(d) *Evaluation plan.* (10 points) The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation—

(1) Are appropriate for the project;

(2) To the extent possible, are objective and produce data that are quantifiable, including, but not limited to, the number of trainees graduated and hired; and

(3) Provide evidence that evaluation data and student follow-up data are systematically collected and used to modify and improve the program. (See 34 CFR 75.590, Evaluation by the grantee.)

(e) *Budget and cost-effectiveness.* (10 points) The Secretary reviews each application to determine the extent to which—

(1) The budget for the project is adequate to support the project activities;

(2) Costs are reasonable in relation to the objectives of the project; and

(3) The applicant presents appropriate plans for the institutionalization of Federally supported activities into basic program operations.

#### Instructions for Transmittal of Applications

(a) If an applicant wants to apply for a grant, the applicant shall—

(1) Mail the original and two copies of the application on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA #84.029), Washington, DC 20202-4725.

or

(2) Hand deliver the original and two copies of the application by 4:30 p.m. (Washington, DC time) on the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA #84.029), room #3633, Regional Office Building #3, 7th and D Streets, SW., Washington, DC 20202.

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

**Notes:** (1) The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

(2) The Application Control Center will mail a Grant Application Receipt Acknowledgement to each applicant. If an applicant fails to receive the notification of application receipt within 15 days from the date of mailing the application, the applicant should call the U.S. Department of Education Application Control Center at (202) 708-9494.

(3) The applicant must indicate on the envelope and—if not provided by the Department—in item 10 of the Application for Federal Assistance (Standard Form 424) the CFDA number—and suffix letter, if any—of the competition under which the application is being submitted.

#### Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 (Intergovernmental Review of Federal Programs) and the regulations in 34 CFR Part 79.

The objective of the Executive Order is to foster an intergovernmental partnership and to strengthen federalism by relying on State and local government coordination and review of proposed Federal financial assistance.

Applicants must contact the appropriate State Single Point of Contact to find out about, and to comply with, the State's process under Executive Order 12372. Applicants proposing to perform activities in more than one State should immediately contact the Single Point of Contact for each of those States and follow the procedure established in each State under the Executive Order. If you want to know the name and address of any State Single Point of Contact, see the list published in the *Federal Register* on September 17, 1990 (55 FR 38210 and 38211).

In States that have not established a process or chosen a program for review, State, areawide, regional, and local entities may submit comments directly to the Department.

Any State Process Recommendation and other comments submitted by a State Single Point of Contact and any comments from State, areawide, regional, and local entities must be mailed or hand-delivered by the date indicated in this notice to the following address: The Secretary, E.O. 12372—CFDA #84.029, U.S. Department of Education, room 4161, 400 Maryland Avenue, SW., Washington, DC 20202-0125.

Proof of mailing will be determined on the same basis as applications (see 34 CFR 75.102). Recommendations or comments may be hand-delivered until 4:30 p.m. (Washington, DC time) on the date indicated in this notice.

**Please Note:** That the above address is not the same address as the one to which the applicant submits its completed application. Do not send applications to the above address. Application instructions and forms.

The appendix to this application is divided into three sections plus a section on common questions and answers, a statement regarding



estimated public reporting burden, and various assurances and certifications. These parts and additional materials are organized in the same manner that the submitted applications should be organized. The parts and additional materials are as follows:

Part I: Application for Federal Assistance (Standard Form 424 (Rev. 4-88)) and instructions.

Part II: Budget Information—Non-Construction Programs (Standard Form 424A) and instructions.

### Part III: Application Narrative.

#### Additional Materials

Estimated Public Reporting Burden. Assurances—Non-Construction Programs (Standard Form 424B).

Certifications regarding Lobbying; Debarment, Suspension, and Other Responsibility Matters; and Drug-Free Workplace Requirements (ED 80-0013).

Certification regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED 80-0014, 9/90) and instructions.

**Note:** ED 80-0014 is intended for the use of grantees and should not be transmitted to the Department.)

Disclosure of Lobbying Activities (Standard Form LLL) (if applicable) and instructions; and Disclosure of Lobbying Activities Continuation Sheet (Standard Form LLL-A).

An applicant may submit information on a photostatic copy of the application and budget forms, the assurances, and the certifications. However, the application form, the assurances, and the certifications must each have an original signature. No grant may be awarded unless a completed application form has been received.

Authority: 20 U.S.C. 1431.

Dated: November 4, 1991.

Robert R. Davila,

Assistant Secretary, Office of Special Education and Rehabilitative.

### Appendix

#### Application Forms and Instructions

Applicants are advised to reproduce and complete the application forms in this section. Applicants are required to submit an original and two copies of each application as provided in this section.

#### Common Questions and Answers

While we have always made every effort to make our application materials as clear and complete as possible, a major task of Division of Personnel Preparation staff from the date of the program announcement to the closing

date is answering phone and mail requests with further questions. The next several pages list some of the most common issues raised by potential applicants in interpreting our regulations and application instructions.

The following issues are not hypothetical. They represent concerns repeatedly raised, even though in many cases they are answered in the regulations or application instructions. The problem seems to be that the issues are not sufficiently highlighted, or that they are disguised by the formal language of legislative documents. These issues and general responses are listed in approximately the frequency of occurrence.

- **Extension of Deadlines.** Waivers for individual applications are not granted, regardless of the circumstances. Under very extraordinary circumstances a closing date may be changed. Such changes are announced in the Federal Register and apply to all applications.

- **Copies of the Application.** Current Government-wide policy is that only an original and two copies need to be submitted. Division staff duplicate the two additional copies necessary to complete the review process by staff and peer readers. It is not required that applications be bound, though they may be if you wish. However, to facilitate our reproduction, please leave one copy unbound. Also, please do not use colored paper, foldouts, photographs, or other hard to duplicate materials. Some applicants prefer to make their own additional copies. If you do so, there is no need to submit more than two additional copies, as that is all that will be required for the review process.

- **Help Preparing Applications.** We are happy to provide general program information. Clearly it would not be appropriate for the staff to participate in the actual writing of an application, but we can respond to specific questions about our application requirements and evaluation criteria, or about the announced priority. Applicants should understand that such previous contact is not required, nor does it guarantee the success of an application.

- **Notification of Funding.** The time required to complete the evaluation of applications is extremely variable. Once applications have been received staff must determine the areas of expertise needed to appropriately evaluate the applications, identify and contact potential reviewers, convene peer review panels, and summarize and review the recommendations of the review panels. You can expect to receive notification within 1 to 2 months of the application closing date. The requested start date should therefore be

a minimum of 2 months after the closing date.

- **Possibility of Learning the Outcome of Review Panels Prior to Official Notification.** Every year we are called by a number of applicants who have really legitimate reasons for needing to know the outcome of the review prior to official notification. Some applicants need to make job decisions, etc. Regardless of the reason, we cannot share information about the review with anyone prior to officially completing the review process for a competition, nor can we tell you when you will be notified. Please do not call us and ask us for this information. You will be notified as quickly as possible either by a grant negotiator (if your application is recommended for funding) or through a letter to the certifying representative (if your application is not successful).

- **Length of Application.** The Department of Education is making a concerted effort to reduce the volume of paper work in applications to discretionary programs. The following suggestions should assist applicants to prepare applications which will convey the information necessary for the review and selection process, and also save America's forests, professional time and energy. The scope and complexity of projects are too variable to establish firm limits on length. Your application should provide enough information to allow the review panel to evaluate the importance and impact of the project as well as to make knowledgeable judgments about the methods you propose to use (design, subjects, sampling procedures, measures, instruments, data analysis strategies, etc.). Many applications include voluminous appended material. In most cases this material is not useful in the evaluation process. Very few projects require much supporting material. However, it is often helpful to have:

- (1) **Staff Vitae**—when these include each person's title and role in the proposed project and contain only information that is relevant to this proposed project's activities and/or publications. Vitae for consultants and Advisory Council members should be similarly brief.

- (2) **Instruments**—except in the case of generally available and well known instruments.

- (3) **Agreements**—when the participation of an agency other than the applicant is critical to the project. This is particularly critical when an intervention will be implemented within an agency, or when subjects will be drawn from particular agencies. Letters of cooperation should be specific,



indicating agreement to implement a particular intervention or to provide access to a particular group. General letters of support are not useful.

Except for the three items noted above, most appendix material is rarely useful. Typical extraneous materials include:

- (1) Related project descriptions completed by applicant.
  - (2) Maps.
  - (3) State plans.
  - (4) Brochures.
  - (5) Copies of publications.
- *Use of Person Loading Charts.*  
Program officials and applicants often find person loading charts useful

formats for showing project personnel and their time commitments to individual activities. A person loading chart is a tabular representation of major activities by number of days spent by each person involved in each activity, as shown in the following example.

TABLE  
[Person loading chart]

Activity	Time in day(s) by person *			
	Person A	Person B	Person C	Person D
Library Research.....	15	20	0	0
Hire Staff.....	0	0	0	5
Prepare Materials.....	5	25	0	0
Train Raters.....	0	2	0	0
Data Collection.....	60	60	0	0
Data Analysis.....	0	0	25	5
Dissemination (manuscripts, etc.).....	0	1	0	10

\* Note: All figures represent FTE for the academic year.

• *Return of Non-Funded Applications.*  
Because of budget restrictions, we are no longer able to return original copies of applications. Thus, applicants should retain at least one copy of the application. Copies of reviewer comments will be mailed to all applicants.

• *Delivering/Sending Applications to the Competition Manager.* Applications can be mailed or hand delivered, but in either case must go to the Application Control Center at the address listed in the Mailing Instructions in this packet. Delivering/sending the application to the competition manager in the program office may prevent it from being logged in on time to the appropriate competition.

• *Format for Applications.*  
Applications are more likely to receive favorable reviews by panels when they are organized according to the published evaluation criteria. If you prefer to use a different format you may wish to cross-reference the sections of your application to the evaluation criteria to be sure that reviewers are able to find all relevant information.

• *Allowed Travel Under These Projects.* Travel associated with carrying out the project is allowed (i.e. travel for data collection, etc.). Travel to conferences is the travel item that is most likely to be questioned during negotiations. Such travel is sometimes allowed when it is for purposes of dissemination, when there will be results to be disseminated, and when it is clear that a conference presentation or workshop is an effective way of reaching a particular target group.

• *Funding of Approved Applications.*  
It is often the case that the number of applications recommended for approval by the reviewers exceeds the dollars available for funding projects under a particular competition. When the panel reviews are completed for a particular competition, the individual reviewer scores and applications are ranked. The higher ranked, approved applications are funded first, and there are often lower ranked, approved applications that do not receive funding. Sometimes the one or two applications that are approved and fall next to rank order (after the projects selected for funding) are placed on hold. If dollars are freed up during negotiations or if a higher ranked applicant declines the award, the projects on hold may receive funding. If you receive a letter stating that you will not receive funding then your project has neither been selected for funding nor placed on hold.

• *Issues Raised During Negotiations.*  
During negotiations technical and budget issues may be raised. These are issues that have been identified during panel and staff review. Generally, technical issues are minor issues that require clarification. Alternative approaches may be presented for your consideration, or you may be asked to provide additional information or rationale for something you have proposed to do. Sometimes issues are stated as "conditions". These are issues that have been identified as so critical that the award cannot be made unless those conditions are met. Questions are also raised about the proposed budget during the negotiation phase. Generally, budget issues are raised because there is

inadequate justification or explanation of the particular budget item, or because the budget item does not seem important to the successful completion of the project. The grants negotiator will present the negotiation questions or issues to you and ask you to respond. If you do not understand the question, you should ask for clarification. In responding to negotiation items you should provide any additional information or clarification requested. You may feel that an issue was addressed in the application. It may not, however, have been explained in enough detail to make it understood by reviewers, and more information should be provided. If you are asked to make changes that you feel could seriously affect the project's success you may provide reasons for not making the changes or provide alternative suggestions. Similarly, if proposed budget reductions will, in your opinion, seriously affect the activities you may want to explain why and provide additional justification for the proposed expenses. Your changes, explanations, and alternative suggestions will be carefully evaluated by staff. In some instances additional negotiations or follow-up information may be needed. In such instances you will again be contacted by the grants negotiator. An award cannot be made until all negotiation issues have been resolved.

#### *Successful Applications and Estimated/Projected Budget Amounts in Subsequent Years*

In this era of budget deficits and need for cost containment, a conservative



policy toward current and out-year budget expenditures is necessary. Projects will not be funded in excess of the amount listed in the **Federal Register** announcement. Any project approved by the reviewers that exceeds the estimated size of award will be required to be performed within the announced amount. The budget estimates that you provide in your application for out-year costs are critical for planning purposes, but they in no way represent a commitment by the Department to a particular level of funding in subsequent years. Budget modifications during the negotiation process, the findings from the initial year, or needed changes in the research design can affect your budget requirements in subsequent years.

However, keep in mind that multi-year projects are likely to be level funded unless there are increases in costs attributable to significant changes in activity level. Grantees having multi-year projects will be asked to submit a continuation application and a detailed budget request prior to each year of the project.

#### *Difference Between a Cooperative Agreement and a Grant*

A cooperative agreement is similar to a grant in that its principal purpose is to accomplish a public purpose of support or stimulation as authorized by a Federal statute. It differs from a grant in the sense that in a cooperative agreement substantial involvement is

anticipated between the executive agency (in this case the Department of Education) and the recipient during the performance of the contemplated activity.

#### *Obtaining Copies of the Federal Register, Program Regulations and Federal Statutes*

Copies of these materials can usually be found at your local library. If not, they can be obtained from the Government Printing Office by writing to: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Telephone: (202) 783-3238.

BILLING CODE 4000-01-M



OMB Approval No. 0348-0043

**APPLICATION FOR  
FEDERAL ASSISTANCE**

<b>1. TYPE OF SUBMISSION:</b> Application <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction Preapplication <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction		<b>2. DATE SUBMITTED</b> _____	Applicant Identifier _____
<b>3. DATE RECEIVED BY STATE</b> _____		State Application Identifier _____	
<b>4. DATE RECEIVED BY FEDERAL AGENCY</b> _____		Federal Identifier _____	

<b>5. APPLICANT INFORMATION</b> Legal Name: _____		Organizational Unit: _____	
Address (give city, county, state, and zip code): _____		Name and telephone number of the person to be contacted on matters involving this application (give area code): _____	

<b>6. EMPLOYER IDENTIFICATION NUMBER (EIN):</b> <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	<b>7. TYPE OF APPLICANT: (enter appropriate letter in box)</b> <input type="checkbox"/> A. State B. County C. Municipal D. Township E. Interstate F. Intermunicipal G. Special District H. Independent School Dist. I. State Controlled Institution of Higher Learning J. Private University K. Indian Tribe L. Individual M. Profit Organization N. Other (Specify) _____
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<b>8. TYPE OF APPLICATION:</b> <input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, enter appropriate letter(s) in box(es): <input type="checkbox"/> <input type="checkbox"/> A. Increase Award    B. Decrease Award    C. Increase Duration D. Decrease Duration    Other (specify): _____	<b>9. NAME OF FEDERAL AGENCY:</b> _____
--	--

<b>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</b> <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div> TITLE: _____	<b>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</b> _____
--	---

<b>12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):</b> _____		<b>13. PROPOSED PROJECT:</b> Start Date: _____ Ending Date: _____	
---	--	--	--

<b>14. CONGRESSIONAL DISTRICTS OF:</b> a. Applicant _____ b. Project _____		<b>15. ESTIMATED FUNDING:</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">a. Federal</td> <td style="width: 10%;">\$</td> <td style="width: 10%;">.00</td> </tr> <tr> <td>b. Applicant</td> <td>\$</td> <td>.00</td> </tr> <tr> <td>c. State</td> <td>\$</td> <td>.00</td> </tr> <tr> <td>d. Local</td> <td>\$</td> <td>.00</td> </tr> <tr> <td>e. Other</td> <td>\$</td> <td>.00</td> </tr> <tr> <td>f. Program Income</td> <td>\$</td> <td>.00</td> </tr> <tr> <td>g. TOTAL</td> <td>\$</td> <td>.00</td> </tr> </table>		a. Federal	\$	.00	b. Applicant	\$	.00	c. State	\$	.00	d. Local	\$	.00	e. Other	\$	.00	f. Program Income	\$	.00	g. TOTAL	\$	.00
a. Federal	\$	.00																						
b. Applicant	\$	.00																						
c. State	\$	.00																						
d. Local	\$	.00																						
e. Other	\$	.00																						
f. Program Income	\$	.00																						
g. TOTAL	\$	.00																						

<b>16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</b> a. YES THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON DATE _____ b. NO <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372 <input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW	<b>17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?</b> <input type="checkbox"/> Yes If "Yes," attach an explanation. <input type="checkbox"/> No
---	--

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.		
a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV. 4-88)  
Prescribed by OMB Circular A-102

Authorized for Local Reproduction



## INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

- | Item: | Entry:   | Item: | Entry:   |
|-------|--|-------|--|
| 1.    | Self-explanatory.  | 12.   | List only the largest political entities affected (e.g., State, counties, cities).   |
| 2.    | Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).  | 13.   | Self-explanatory.  |
| 3.    | State use only (if applicable).  | 14.   | List the applicant's Congressional District and any District(s) affected by the program or project.  |
| 4.    | If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.  | 15.   | Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate <u>only</u> the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15. |
| 5.    | Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.   | 16.   | Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.  |
| 6.    | Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.  | 17.   | This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.  |
| 7.    | Enter the appropriate letter in the space provided.  | 18.   | To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)  |
| 8.    | Check appropriate box and enter appropriate letter(s) in the space(s) provided:<br>— "New" means a new assistance award.<br>— "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.<br>— "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. |       |  |
| 9.    | Name of Federal agency from which assistance is being requested with this application.   |       |  |
| 10.   | Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.  |       |  |
| 11.   | Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.  |       |  |



**Instructions for Estimated Public Reporting Burden**

Under terms of the Paperwork Reduction Act of 1980, as amended, and the regulations implementing that Act, the Department of Education invited comment on the public reporting burden in this collection of information. Public reporting burden for this collection of information is estimated to average 36

hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. You may send comments regarding this burden estimate or any other aspect of this collection of the information, including suggestions for reducing this burden, to the U.S.

Department of Education, Information Management and Compliance Division, Washington, DC 20202-4651; and to the Office of Management and Budget, Paperwork Reduction Project 1820-0028, Washington, DC 20503.

(Information collection approved under OMB Control number 1820-0028. Expiration date: 7/31/92.)

BILLING CODE 4000-01-M



OMB Approval No. 0348-0044

## BUDGET INFORMATION — Non-Construction Programs

## SECTION A — BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		\$	\$	\$	\$	\$
2.						
3.						
4.						
5. TOTALS		\$	\$	\$	\$	\$

## SECTION B — BUDGET CATEGORIES

Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY					Total (5)
	(1)	(2)	(3)	(4)	(5)	
a. Personnel	\$	\$	\$	\$	\$	\$
b. Fringe Benefits						
c. Travel						
d. Equipment						
e. Supplies						
f. Contractual						
g. Construction						
h. Other						
i. Total Direct Charges (sum of 6a - 6h)						
j. Indirect Charges						
k. TOTALS (sum of 6i and 6j)	\$	\$	\$	\$	\$	\$
7. Program Income	\$	\$	\$	\$	\$	\$

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4/3

Standard Form 424A (4-89)  
Prescribed by OMB Circular A-102



SECTION C - NON-FEDERAL RESOURCES					
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS	
8.	\$	\$	\$	\$	
9.					
10.					
11.					
12. TOTALS (sum of lines 8 and 11)	\$	\$	\$	\$	
SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
	\$	\$	\$	\$	\$
13. Federal					
14. NonFederal					
15. TOTAL (sum of lines 13 and 14)	\$	\$	\$	\$	\$
SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT					
(a) Grant Program	FUTURE FUNDING PERIODS (Years)				(e) Fourth
	(b) First	(c) Second	(d) Third		
16.	\$	\$	\$	\$	\$
17.					
18.					
19.					
20. TOTALS (sum of lines 16-19)	\$	\$	\$	\$	\$
SECTION F - OTHER BUDGET INFORMATION (Attach additional Sheets if Necessary)					
21. Direct Charges:	22. Indirect Charges:				
23. Remarks					



## INSTRUCTIONS FOR THE SF-424A

## General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

**Section A. Budget Summary**  
Lines 1-4, Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the catalog program title and the catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in Column (a) and the respective catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

**Lines 1-4, Columns (c) through (g.)**

For *new applications*, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

**Lines 1-4, Columns (c) through (g.) (continued)**

For *continuing grant program applications*, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For *supplemental grants and changes* to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

**Line 5** — Show the totals for all columns used.

**Section B Budget Categories**

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

**Lines 6a-i** — Show the totals of Lines 6a to 6h in each column.

**Line 6j** — Show the amount of indirect cost.

**Line 6k** — Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.



**INSTRUCTIONS FOR THE SF-424A (continued)**

**Line 7** - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the federal grantor agency in determining the total amount of the grant.

**Section C. Non-Federal-Resources**

**Lines 8-11** - Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

**Column (a)** - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

**Column (b)** - Enter the contribution to be made by the applicant.

**Column (c)** - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

**Column (d)** - Enter the amount of cash and in-kind contributions to be made from all other sources.

**Column (e)** - Enter totals of Columns (b), (c), and (d).

**Line 12** - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

**Section D. Forecasted Cash Needs**

**Line 13** - Enter the amount of cash needed by quarter from the grantor agency during the first year.

**Line 14** - Enter the amount of cash from all other sources needed by quarter during the first year.

**Line 15** - Enter the totals of amounts on Lines 13 and 14.

**Section E. Budget Estimates of Federal Funds Needed for Balance of the Project**

**Lines 16 - 19** - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

**Line 20** - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

**Section F. Other Budget Information**

**Line 21** - Use this space to explain amounts for individual direct object-class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

**Line 22** - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

**Line 23** - Provide any other explanations or comments deemed necessary.



**ASSURANCES — NON-CONSTRUCTION PROGRAMS**

**Note:** Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.
9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.



10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is \$10,000 or more.
11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).
12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.
13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).
14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.
15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.
16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.
17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.
18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED



## CERTIFICATIONS REGARDING LOBBYING; DEBARMENT, SUSPENSION AND OTHER RESPONSIBILITY MATTERS; AND DRUG-FREE WORKPLACE REQUIREMENTS

Applicants should refer to the regulations cited below to determine the certification to which they are required to attest. Applicants should also review the instructions for certification included in the regulations before completing this form. Signature of this form provides for compliance with certification requirements under 34 CFR Part 82, "New Restrictions on Lobbying," and 34 CFR Part 85, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." The certifications shall be treated as a material representation of fact upon which reliance will be placed when the Department of Education determines to award the covered transaction, grant, or cooperative agreement.

### 1. LOBBYING

As required by Section 1352, Title 31 of the U.S. Code, and implemented at 34 CFR Part 82, for persons entering into a grant or cooperative agreement over \$100,000, as defined at 34 CFR Part 82, Sections 82.105 and 82.110, the applicant certifies that:

- (a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement;
- (b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions;
- (c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all subrecipients shall certify and disclose accordingly.

### 2. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS

As required by Executive Order 12549, Debarment and Suspension, and implemented at 34 CFR Part 85, for prospective participants in primary covered transactions, as defined at 34 CFR Part 85, Sections 85.105 and 85.110 -

#### A. The applicant certifies that it and its principals:

- (a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
- (b) Have not within a three-year period preceding this application been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
- (c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application had one or more public transactions (Federal, State, or local) terminated for cause or default; and

B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.

### 3. DRUG-FREE WORKPLACE (GRANTEES OTHER THAN INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610 -

A. The applicant certifies that it will or will continue to provide a drug-free workplace by:

- (a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
- (b) Establishing an on-going drug-free awareness program to inform employees about-
  - (1) The dangers of drug abuse in the workplace;
  - (2) The grantee's policy of maintaining a drug-free workplace;
  - (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
  - (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
- (c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
- (d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will-
  - (1) Abide by the terms of the statement; and
  - (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;
- (e) Notifying the agency, in writing, within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, S.W. (Room 3124, GSA Regional Office



Building No. 3), Washington, DC 20202-4571. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted—

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

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Check ☐ if there are workplaces on file that are not identified here.

### DRUG-FREE WORKPLACE (GRANTEES WHO ARE INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610 --

A. As a condition of the grant, I certify that I will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant; and

B. If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, I will report the conviction, in writing, within 10 calendar days of the conviction, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, S.W. (Room 3124, GSA Regional Office Building No. 3), Washington, DC 20202-4571. Notice shall include the identification number(s) of each affected grant.

As the duly authorized representative of the applicant, I hereby certify that the applicant will comply with the above certifications.

NAME OF APPLICANT	PR/AWARD NUMBER AND/OR PROJECT NAME
PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	
SIGNATURE	DATE



## Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion – Lower Tier Covered Transactions

This certification is required by the Department of Education regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, for all lower tier transactions meeting the threshold and tier requirements stated at Section 85.110.

### Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.
2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.
5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.
6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.
8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

### Certification

- (1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.
- (2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

NAME OF APPLICANT	PR / AWARD NUMBER AND/OR PROJECT NAME
PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	
SIGNATURE	DATE



**DISCLOSURE OF LOBBYING ACTIVITIES**Approved by OMB  
6348-0046Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352  
(See reverse for public burden disclosure.)

<b>1. Type of Federal Action:</b> <input type="checkbox"/> a. contract <input type="checkbox"/> b. grant <input type="checkbox"/> c. cooperative agreement <input type="checkbox"/> d. loan <input type="checkbox"/> e. loan guarantee <input type="checkbox"/> f. loan insurance	<b>2. Status of Federal Action:</b> <input type="checkbox"/> a. bid/offer/application <input type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award	<b>3. Report Type:</b> <input type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change For Material Change Only: year _____ quarter _____ date of last report _____
<b>4. Name and Address of Reporting Entity:</b> <input type="checkbox"/> Prime <input type="checkbox"/> Subawardee Tier _____, if known:  Congressional District, if known: _____	<b>5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime:</b>  Congressional District, if known: _____	
<b>6. Federal Department/Agency:</b>	<b>7. Federal Program Name/Description:</b>  CFDA Number, if applicable: _____	
<b>8. Federal Action Number, if known:</b>	<b>9. Award Amount, if known:</b> \$ _____	
<b>10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI):</b>  <div style="border: 1px solid black; height: 100px; width: 100%;"></div>		
<b>b. Individuals Performing Services (including address if different from No. 10a) (last name, first name, MI):</b>  <div style="border: 1px solid black; height: 100px; width: 100%;"></div>		
<small>(attach Continuation Sheet(s) SF-LLL-A, if necessary)</small>		
<b>11. Amount of Payment (check all that apply):</b> \$ _____ <input type="checkbox"/> actual <input type="checkbox"/> planned	<b>13. Type of Payment (check all that apply):</b> <input type="checkbox"/> a. retainer <input type="checkbox"/> b. one-time fee <input type="checkbox"/> c. commission <input type="checkbox"/> d. contingent fee <input type="checkbox"/> e. deferred <input type="checkbox"/> f. other; specify: _____	
<b>12. Form of Payment (check all that apply):</b> <input type="checkbox"/> a. cash <input type="checkbox"/> b. in-kind; specify: nature _____ value _____		
<b>14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11:</b>  <div style="border: 1px solid black; height: 100px; width: 100%;"></div>		
<small>(attach Continuation Sheet(s) SF-LLL-A, if necessary)</small>		
<b>15. Continuation Sheet(s) SF-LLL-A attached:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.</b>	<b>Signature:</b> _____ <b>Print Name:</b> _____ <b>Title:</b> _____ <b>Telephone No.:</b> _____ <b>Date:</b> _____	
<b>Federal Use Only:</b>		<b>Authorized for Local Reproduction</b> <b>Standard Form - LLL</b>



**INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES**

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.  
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.



**DISCLOSURE OF LOBBYING ACTIVITIES  
CONTINUATION SHEET**

Approved by OMB:  
0348-0046

Reporting Entity: \_\_\_\_\_ Page \_\_\_\_\_ of \_\_\_\_\_







# Indian Register

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Thursday  
November 7, 1991

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## Part VIII

### Department of the Interior

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#### Bureau of Indian Affairs

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Chickamauga Cherokee Indian Nation of  
Arkansas and Missouri; Receipt of Petition  
for Federal Acknowledgment of Existence  
as an Indian Tribe; Notice



**DEPARTMENT OF THE INTERIOR****Bureau of Indian Affairs****Chickamauga Cherokee Indian Nation of Arkansas and Missouri; Receipt of Petition for Federal Acknowledgment of Existence as an Indian Tribe**

October 25, 1991.

This is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indians Affairs by 209 DM 8.

Pursuant to 25 CFR 83.8(a) (formerly 25 CFR 54.8(a)) notice is hereby given that the Chickamauga Cherokee Indian Nation of Arkansas and Missouri, c/o Donald E. Coones, P.O. Box 243, Hardy, AR 72542; or 217 Forest Lane, Republic, Missouri 65738, has filed a petition for

acknowledgment by the Secretary of the Interior that the group exists as an Indian tribe. The petition was received by the Bureau of Indian Affairs (BIA) on September 5, 1991, and was signed by members of the group's governing body.

This is a notice of receipt of petition and does not constitute notice that the petition is under active consideration. Notice of active consideration will be sent by mail to the petitioner and other interested parties at the appropriate time.

Under § 83.8(d) (formerly § 54.8(d)) of the Federal regulations, interested parties may submit factual and/or legal arguments in support of or in opposition to the group's petition. Any information submitted will be made available on the same basis as other information in the

BIA's files. Such submissions will be provided to the petitioner upon receipt by the BIA. The petitioner will be provided an opportunity to respond to such submissions prior to a final determination regarding the petitioner's status.

The petition may be examined by appointment in the Department of the Interior, Bureau of Indian Affairs, Branch of Acknowledgment and Research, room 1362-MIB, 1849 C Street, NW., Washington, DC 20240, phone (202) 208-3592.

**David J. Matheson,**

*Acting Assistant Secretary—Indian Affairs.*

[FR Doc. 91-26891 Filed 11-6-91; 8:45 am]

**BILLING CODE 4310-02-M**



# Reader Aids

Federal Register

Vol. 56, No. 216

Thursday, November 7, 1991

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### 3 CFR

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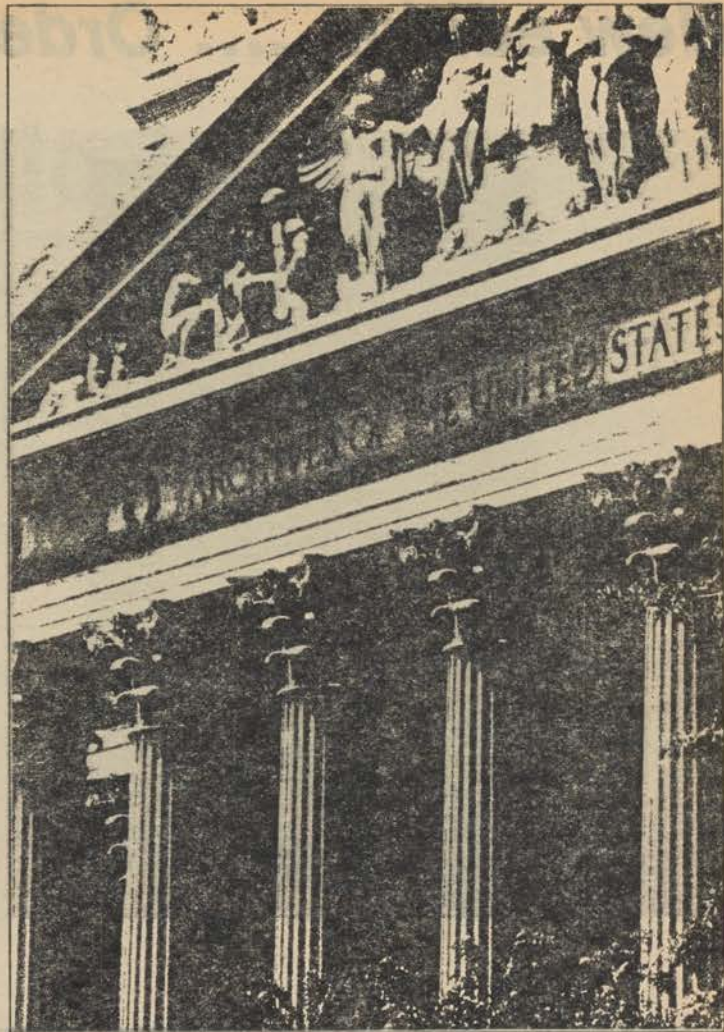
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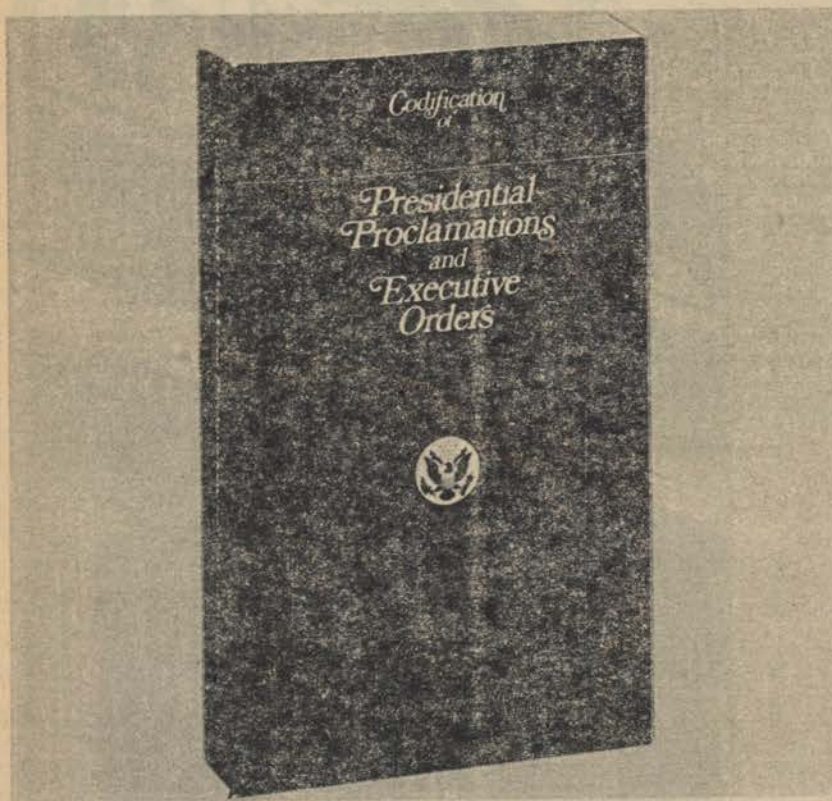
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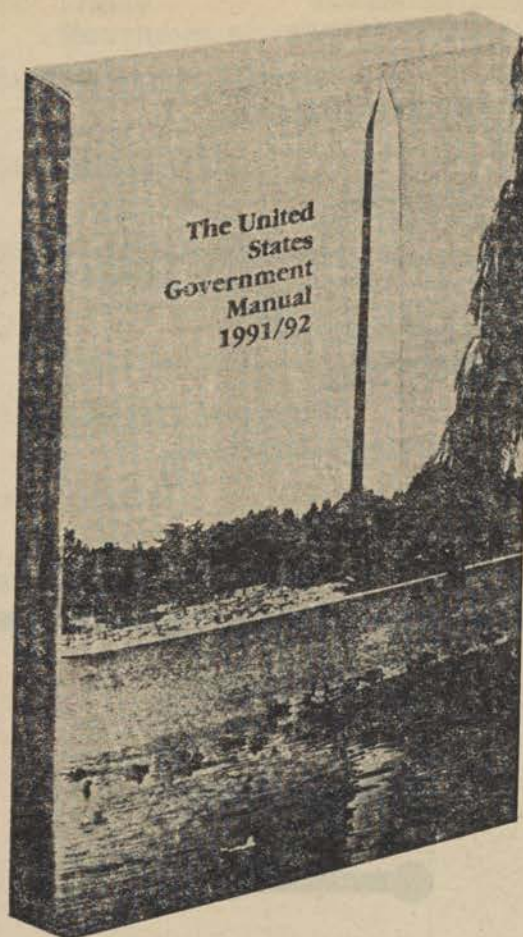
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